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PTO/SB/17 (10-07)
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Effective on 12/08/2004.
Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL
For FY 2008

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 510.00

Complete if Known	
Application Number	10/750,139
Filing Date	June 3, 2004
First Named Inventor	Jessica DesNoyer
Examiner Name	James William Rogers
Art Unit	1618
Attorney Docket No.	50623.326

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____

☑ Deposit Account Deposit Account Number: 07-1850 Deposit Account Name: Squire Sanders & Dempsey

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☑ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, **except for the filing fee**

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FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

	FILING FEES		SEARCH FEES		EXAMINATION FEES		
		Small Entity		Small Entity		Small Entity	
Application Type	Fee ($)	Fee ($)	Fee ($)	Fee ($)	Fee ($)	Fee ($)	Fees Paid ($)
Utility	310	155	510	255	210	105	
Design	210	105	100	50	130	65	
Plant	210	105	310	155	160	80	
Reissue	310	155	510	255	620	310	
Provisional	210	105	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	Fee ($)	Small Entity Fee ($)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	210	105
Multiple dependent claims	370	185

Total Claims		Extra Claims	Fee ($)		Fee Paid ($)
_____	- 20 or HP =	_____	x _____	=	_____

HP = highest number of total claims paid for, if greater than 20.

Indep. Claims		Extra Claims	Fee ($)		Fee Paid ($)
_____	- 3 or HP =	_____	x _____	=	_____

HP = highest number of independent claims paid for, if greater than 3.

Multiple Dependent Claims	
Fee ($)	Fee Paid ($)
_____	_____

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is $260 ($130 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets		Extra Sheets		Number of each additional 50 or fraction thereof		Fee ($)		Fee Paid ($)
_____	- 100 =	_____	/ 50 =	_____	(round **up** to a whole number) x	_____	=	_____

4. OTHER FEE(S)

	Fees Paid ($)
Non-English Specification, $130 fee (no small entity discount)	
Other (e.g., late filing surcharge): Appeal Brief	510.00

SUBMITTED BY

Signature		Registration No. (Attorney/Agent) 46,872	Telephone 415 393-9885
Name (Print/Type)	Zhaoyang Li, Ph.D.		Date March 3, 2008

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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission: 432

Application Number	10/750,139
Filing Date	June 3, 2004
First Named Inventor	Jessica DesNoyer
Art Unit	1618
Examiner Name	James William Rogers
Attorney Docket Number	50623.326

ENCLOSURES *(Check all that apply)*

- [✓] Fee Transmittal Form
  - [ ] Fee Attached
- [ ] Amendment/Reply
  - [ ] After Final
  - [ ] Affidavits/declaration(s)
- [ ] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Reply to Missing Parts/ Incomplete Application
  - [ ] Reply to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [ ] Petition
- [ ] Petition to Convert to a Provisional Application
- [ ] Power of Attorney, Revocation Change of Correspondence Address
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s) _____
  - [ ] Landscape Table on CD
- [ ] After Allowance Communication to TC
- [ ] Appeal Communication to Board of Appeals and Interferences
- [✓] Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- [ ] Proprietary Information
- [ ] Status Letter
- [✓] Other Enclosure(s) (please Identify below):
  1. Return Receipt Postcard
  2. Appendices A-Q

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Squire Sanders & Dempsey, LLP		
Signature			
Printed name	Zhaoyang Li, Ph.D.		
Date	March 3, 2008	Reg. No.	46,872

CERTIFICATE OF TRANSMISSION/MAILING

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Signature			
Typed or printed name	La Renda Meyer (Via Express Mail Label No. EM 140485693 US	Date	March 3, 2008

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Application No. 10/750,139

Attorney Docket 50623.326

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application Of:	Examiner: James William Rogers
DesNoyer et al.	Art Unit: 1618
Serial No: 10/750,139	
Filed: June 3, 2004	
For: Poly(Ester Amide) Coating Composition For Implantable Devices	

Mail Stop: **Appeal Brief-Patents**
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

Dear Sir:

This Appeal Brief is submitted pursuant to receipt of an Office Communication mailed on October 10, 2007 and an Advisory Action mailed on January 30, 2008, in which the examiner maintained his rejection of claims 1-58.

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REAL PARTY IN INTEREST

The real party in interest with regard to this appeal is Advanced Cardiovascular Systems Inc., a California corporation, having a place of business at 3200 Lakeside Drive, Santa Clara, California 95054. The original assignment to Advanced Cardiovascular system Inc. was recorded at Reel/Frame 016359/0760 on March 8, 2005. Effective February 13, 2007, Advanced Cardiovascular Systems Inc. changed its name to Abbott Cardiovascular Systems Inc.

RELATED APPEALS AND INTERFERENCES

There are no appeals or interferences related to or that might have any bearing, direct or indirect, on the Board's decision in this appeal.

STATUS OF CLAIMS

Claims 1-58 are pending in the application.

Claims 1-58 are rejected and form the subject of this appeal.

Claims 1-52 were initially filed in this case as U.S. application No. 10/750,139, filed December 30, 2003. Claims 1, 8, 12, 19, 23, and 30 are independent claims. Claims 2-7 depend from claim 1, claims 9-11 depend from claim 8, claims 13-18 depend from claim 12, claims 20-22 depend from claim 19, claims 24-29, 34-38, 41, 42, 45-49, and 51 depend from claim 23, and claims 31-33, 39, 40, 43, 44, 50, and 52 depend from claim 30. A notice of incomplete application was mailed May 6, 2006. In response, Applicants submitted Figure 1 on June 3, 2004. The application was granted a filing date of June 3, 2004. In an office action mailed August 1, 2006 (**Evidence Appendix, "A"**), claims 2, 13, and 24 were rejected as being indefinite. Claims 8-11, 19-22, 30-33, 39, 43, 44, 50, and 52 were rejected as being anticipated by U.S. patent application publication No. 20050149173 by Hunter et al. ("Hunter"), which received the benefit of provisional filing date of November 20, 2003 (**Evidence Appendix, "B"**). Claims 1-52 were rejected as being obvious over Hunter in view of U.S. patent application publication No. 20020123803 by Pacetti et al. ("Pacetti") (**Evidence Appendix, "C"**). Applicants responded on November 1, 2006 (**Evidence Appendix, "D"**). In the response, Applicants added claims 53-58, which depends from claims 1, 8, 12, 19, 23

and 30, respectively. Applicants pointed out that Hunter does not describe or teach a coating having a poly(ester amide) (PEA) polymer and at least one low surface energy polymer that is biologically benign since the polymer disclosed by Hunter would induce fibrosis between a device comprising the polymer and the host tissue. Applicants argued that claims 8-11, 19-22, 30-33, 39, 43, 44, 50, and 52 are novel over Hunter. Applicants further pointed out that Hunter in view of Pacetti does not provide for the subject matter defined by any of claims 1-52 and argued that the claims are non-obvious over Hunter in view of Pacetti. Applicants also filed a Declaration under 37 CFR §1.131, indicating Applicants conceived the subject matter of the instant application prior to November 10, 2003.

On December 27, 2006, the examiner mailed a final office action (**Evidence Appendix, "E"**), in which the examiner withdrew all the rejections previously made but rejected claims 1-58 as being obvious over WO 03/022323 by Pacetti ("Pacetti 2") (**Evidence Appendix, "F"**) in view of WO 98/32398 by Roby et al. ("Roby") (**Evidence Appendix, "G"**). The examiner argued Pacetti 2 discloses polyurethanes with polydimethylsiloxane soft segments, poly(vinylidene fluoride-co-methacrylic acid) and Roby discloses a poly(ester amide) (PEA). Applicants responded on February 12, 2007 (**Evidence Appendix, "H"**), filing a Statement of Common Ownership to demonstrate that Pacetti 2 and the present application are commonly owned to disqualify Pacetti 2 as prior art. Applicants pointed out that Roby does not provide for a coating comprising a PEA polymer and a low surface energy, surface blooming polymer and argued that the claims are non-obvious over Roby. On March 16, 2007, an Advisory Action was mailed (**Evidence Appendix, "I"**), in which the examiner indicated that Pacetti 2 was published more than a year prior to the filing date of the present application and therefore cannot be disqualified as prior art. In response, Applicants amended claim 1 and other independent claims to define the low energy, surface blooming polymer as comprising a PEA miscible block or PEA miscible backbone and filed a Request for Continued Examination (RCE) (**Evidence Appendix, "J"**). Applicants argued that the claims are non-obvious over Pacetti 2 in view of Roby.

On June 12, 2005, the examiner mailed an office action (**Evidence Appendix, "K"**), objecting to claims 6, 7, 17, 18, 28 and 29 as being improper form because a multiply dependent claim cannot depend upon another multiply dependent claim and

rejecting again claims 1-58 as being obvious over Pacetti 2 in view of Roby. The examiner argued that Pacetti 2 discloses polyurethanes with polydimethylsiloxane soft segments, poly(vinylidene fluoride-co-methacrylic acid), styrene-ethylene-styrene block copolymer, polytetrafluoroethylene, etc. and that Pacetti 2 and Roby would make obvious the combination of PEA and a low energy, surface blooming polymer comprising a PEA miscible block or PEA miscible backbone as defined in the claims. In a Response and Amendment to Office Action mailed September 12, 2007, Applicants pointed out that claims 6, 7, 17, 18, 28 and 29 are proper multiply dependent claims under 37 CFR 1.75(c) and deleted polyurethane, styrene-butadiene-styrene block copolymer, and styrene-butylene/ethylene-styrene block copolymer from the definition of the low energy, surface blooming polymer (**Evidence Appendix, "L"**). Applicants argued that Pacetti and Roby in combination fail to provide a low energy, surface blooming polymer as defined by the claims and thus claims 1-58 are non-obvious over Pacetti 2 over Roby.

On October 10, 2007, the examiner mailed a Final Office Action (**Evidence Appendix, "M"**), in which the examiner rejected claim 4 as being obvious over Roby in view of U.S. patent application publication No. 2002/0107330 by Pinhcuck et al. ("Pinhcuck") (**Evidence Appendix, "N"**). The examiner noted that Roby does not describe teach a low energy, surface blooming polymer as defined by claim 4 but argued that Pinhcuck discloses a copolymer that includes blocks such as polycaprolactone, polyglycolic acid, siloxane polymers and the like, which the examiner argued would meet the definition of low energy, surface blooming polymer as recited in claim 4. The examiner remained the rejection of claims 1-3 and 5-58 as being obvious over Pacetti 2 in view of Roby, alleging polyurethanes with a polydimethylsiloxane soft segment would meet the definition of a low surface energy surface blooming polymer or polymer additive. Applicants responded on January 7, 2008, pointing out that either the combination of Roby and Pinhcuck or of Pacetti 2 and Roby fail to provide for the element of a low energy, surface blooming polymer or additive as defined in the claims and polyurethane is deleted from the definition of a PEA miscible block or PEA miscible backbone as defined in the claims (**Evidence Appendix, "O"**). A Notice of Appeal (**Evidence Appendix, "P"**) was filed with the response to final office action.

On January 30, 2008, the examiner mailed an Advisory Action (**Evidence Appendix, "Q"**), maintaining the rejections of claims as set forth in the Final Office Action mailed October 10, 2007.

The Response to Final Office Action filed on January 7, 2008 includes no amendment to the claims. Thus, claims1-58 as currently pending are the subject of this appeal.

STATUS OF AMENDMENTS

As indicated above, the Response to Final Office Action filed on January 7, 2008 includes no amendment to the claims. Thus, amendments in the Response to Office Action filed September 12, 2007 and prior amendments have been entered and are before the Board.

SUMMARY OF THE CLAIMED SUBJECT MATTER

Claims 1-11, 53, and 54 are drawn to methods of forming a coating on an implantable device.

Claims 12-22, 55 and 56 are drawn to a coating composition.

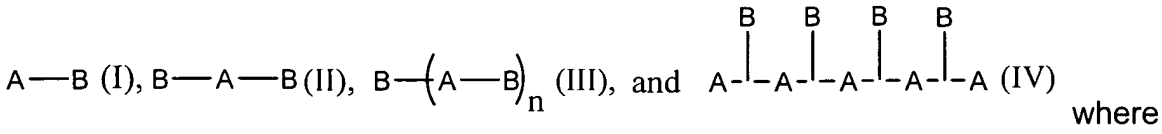
Claims 23-44, 57 and 58 are drawn to an implantable device.

Claims 45-52 are drawn to a method of treating a disorder.

Claims 1, 8, 12, 19, 23, and 30 are independent claims. Claim 4, which is also argued, depends from claim 1. The subject matter of these claims is discussed below.

Claim 1 defines a method for forming a poly(ester amide) (PEA) coating with enhanced mechanical and release rate properties. The method comprises the acts of: applying to an implantable device a solution or suspension of a composition comprising a PEA and a low surface energy, surface blooming polymer, and forming a coating on the implantable device comprising PEA and the low surface energy, surface blooming polymer. The low surface energy, surface blooming polymer comprises a PEA miscible block or PEA miscible backbone.

Claim 4 depends from claim 1 and further defines the low surface energy polymer as being one of formulae I-IV of the following structure:



where

A is the PEA miscible block or PEA miscible backbone, and B is a surface blooming block or a surface blooming pendant group. A is further defined to be, among others, poly(ester-urea) urethane, poly(ether-urethane), poly(ester-urethane), poly(carbonate-urethane), poly(silicone-urethane), or poly(urea-urethane). B is one of a linear or branched alkyl chain, polysilanes, polysiloxanes, poly(dimethylsiloxane), a linear or branched perfluoro chain, and a combination thereof.

Claim 8 defines a method for forming a poly(ester amide) (PEA) coating with enhanced mechanical and release rate properties. The method comprises the acts of applying to an implantable device a solution or suspension of a composition comprising a PEA and at least one low surface energy polymer additive, and forming a coating on the implantable device comprising PEA and the at least one low surface energy polymer additive. The at least one low surface energy polymer additive comprises a PEA miscible block or PEA miscible backbone.

Claim 19 defines a coating composition for coating an implantable device comprising a poly(ester amide) (PEA) and at least one low surface energy polymer additive. The at least one low surface energy polymer additive comprises a PEA miscible block or PEA miscible backbone.

Claim 23 defines an implantable device comprising a coating which comprises a poly(ester amide) (PEA) and a low surface energy, surface blooming polymer. The low surface energy, surface blooming polymer comprises a PEA miscible block or PEA miscible backbone.

Claim 30 defines an implantable device comprising a coating which comprises a poly(ester amide) (PEA) and at least one low surface energy polymer additive. The at least one low surface energy polymer additive comprises a PEA miscible block or PEA miscible backbone.

Support for claims 1 and 4 can be found at least at least at page 6, lines 11 to 20; page 7, line 10 to page 8, line 3; page 9, lines 1-7; and page 14, line 20 to page 16, line 2.

Support for claim 8 can be found at least at least at page 6, line 11 to page 7, line 9; page 9, lines 1-7; and page 14, line 20 to page 16, line 2.

Support for claim 19 can be found at least at least at page 6, line 11 to page 7, line 9 and page 9, lines 1-7.

Support for claim 23 can be found at least at least at page 6, lines 11 to 20; page 7, line 10 to page 8, line 3; page 9, lines 1-7; and page 17, lines 3-22.

Support for claim 8 can be found at least at least at page 6, line 11 to page 7, line 9; page 9, lines 1-7; and page 17, lines 3-22.

The complete claim set as currently entered is provided in the **Claims Appendix**.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The issues presented in this appeal are:

(1) Whether claim 4 is obvious over Roby in view of Pinhcuck under 35 U.S.C. 103(a); and

(2) Whether claims 1-3, and 5-58 obvious over Pacetti 2 in view of Roby under 35 U.S.C. 103(a).

ARGUMENT

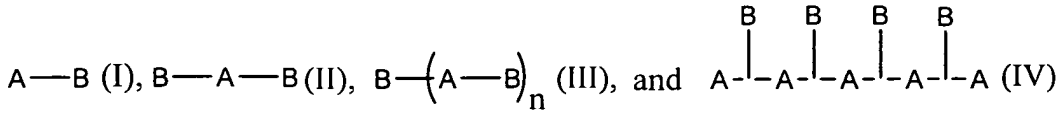
(1). Claim 4 is non-obvious over Roby in view of Pinhcuck under 35 U.S.C. 103(a)

A. The Law

Claims are non-obvious if the claimed subject matter is more than a predictable use of prior art elements according to their established functions (see, KSR International Co. v. Teleflex, Inc., 550 U.S. ____, Slip Opinion No. 04-1350, page 13 (2007)).

B. Analysis

Claim 4 is drawn to a method of forming a coating on a medical device. The coating includes a PEA polymer and a low energy, surface blooming polymer, which has a PEA miscible block or PEA miscible backbone. The low surface energy polymer is one of formulae I-IV of the following structure:



where **A is the PEA miscible block or PEA miscible backbone, and B is a surface blooming block or a surface blooming pendant group**. A is further defined to be, among others, poly(ester-urea) urethane, poly(ether-urethane), poly(ester-urethane), poly(carbonate-urethane), poly(silicone-urethane), or poly(urea-urethane). B is one of a linear or branched alkyl chain, polysilanes, polysiloxanes, poly(dimethylsiloxane), a linear or branched perfluoro chain, and a combination thereof.

a) Roby

Roby discloses the preparation of a poly(ester amide) (PEA) polymer that can be used for fabrication of surgical devices. However, Roby does not describe or teach using a PEA polymer blend to form a coating. Further, Roby does not recognize that the properties of a coating including a PEA polymer can be improved using a low surface energy, surface blooming polymer, the low surface energy, surface blooming polymer including a PEA miscible block or PEA miscible backbone.

b) Pinhcuck

Pinhcuck discloses coatings that can be formed of a polymer that can include an A block and a B block. The A block can be a polyolefin, and the B block can be from a methacrylate monomer. At paragraph [0016], Pinhcuck indicates that the coating can further include a block copolymer including one or more of ... a polyurethane, a silicone, or a siloxane polymer. The block copolymer disclosed by Pinhcuck is clearly different from the low surface energy, surface blooming polymer as defined by claim 4, which defines the low surface energy, surface blooming polymer as having a structure of one of formulae I-IV, shown above. Note, the structure of any of formulae I-IV has an A component and a B component where A can be poly(ester-urea) urethane, poly(ether-urethane), poly(ester-urethane), poly(carbonate-urethane), poly(silicone-urethane), or poly(urea-urethane). Pinhcuck does not such an A component. Further, Pinhcuck does not describe or teach using a PEA polymer blend to form a coating. Nor does Pinhcuck recognize that the properties of a coating including a PEA polymer can be improved using a low surface energy, surface blooming polymer, the low surface energy, surface blooming polymer including a PEA miscible block or PEA miscible backbone.

Therefore, Roby and Pinhcuck in combination fail to provide for a coating including a PEA polymer and a low surface energy, surface blooming polymer in general, the low surface energy, surface blooming polymer including a PEA miscible

block or PEA miscible backbone. Further, Roby and Pinhcuck in combination fail to provide for the specific low surface energy, surface blooming polymer as defined by claim 4. As such, Roby and Pinhcuck in combination would not make claim 4 *prima facie* obvious under 35 U.S.C. §103(a) (see MPEP §2141).

(2). Claims 1-3, and 5-58 are non-obvious over Pacetti 2 in view of Roby under 35 U.S.C. 103(a)

A. The Law

Claims are non-obvious if the claimed subject matter is more than a predictable use of prior art elements according to their established functions (see, KSR International Co. v. Teleflex, Inc., 550 U.S. ____, Slip Opinion No. 04-1350, page 13 (2007)).

B. Analysis

a) Claims 1-3, and 5-7 and 53 are non-obvious over Pacetti 2 in view of Roby

Claims 2, 3, 5-7 and 53 depend from claim 1. Claim 1 defines a method for forming a poly(ester amide) (PEA) coating with enhanced mechanical and release rate properties. The method includes (a) applying to an implantable device a solution or suspension of a composition comprising PEA and a low surface energy, surface blooming polymer, and (b) forming a coating on the implantable device comprising PEA and the low surface energy, surface blooming polymer. The low surface energy, surface blooming polymer includes a PEA miscible block or PEA miscible backbone.

Pacetti 2 describes a coating for reducing the release rate of a therapeutic agent from the coating. The coating includes a polymer capable of maintaining its crystalline lattice structure while the therapeutic agent is released from the coating. Pacetti 2 does not describe a coating that includes a PEA. Nor does Pacetti 2 describe or teach forming a coating comprising applying to an implantable device a composition that comprises a PEA polymer and a low surface energy, surface blooming polymer that includes a PEA miscible block or PEA miscible backbone. Nor does Pacetti 2 recognize the need to improve the properties of a coating formed of a PEA polymer using a low surface energy, surface blooming polymer.

As discussed above, Roby discloses the preparation of a poly(ester amide) (PEA) polymer but fails to describe or teach forming a coating comprising applying to an implantable device a composition that comprises a PEA polymer and a low surface

energy, surface blooming polymer that includes a PEA miscible block or PEA miscible backbone. Nor does Roby recognize the need to improve the properties of a coating formed of a PEA polymer using a low surface energy, surface blooming polymer.

Therefore, Pacetti 2 and Roby in combination, fail to provide a PEA polymer blend that includes a PEA polymer and a low surface energy, surface blooming polymer that includes a PEA miscible block or PEA miscible backbone. Further, a person of ordinary skill in the art would not have a reasonable expectation of the subject matter claimed by claim 1; for Pacetti 2 and Roby in combination, fail to recognize that a low surface energy, surface blooming polymer that includes a PEA miscible block or PEA miscible backbone can be used to improve the properties of a coating comprising a PEA polymer. As such, claim 1 is not a predictable variation of the disclosed coating by Pacetti 2 in view of Roby. Therefore, claim 1 is non-obvious over Pacetti 2 and Roby under 35 U.S.C. 103(a). Claims 2, 3 and 5-7 and 53 depend from claim 1 and are non-obvious over Pacetti 2 and Roby under 35 U.S.C. 103(a) for at least the same reason.

b) Claims 8, 9-11 and 54 are non-obvious over Pacetti 2 in view of Roby

Claim 8 defines a method of forming a coating having a PEA polymer and at least one low surface energy polymer additive. The at least one low surface energy polymer additive comprises a PEA miscible block or PEA miscible backbone. As discussed above, Pacetti 2 and Roby fail to teach or suggest the method of forming a coating including a PEA polymer and at least one low surface energy polymer additive comprising a PEA miscible block or PEA miscible backbone. Therefore, claim 8 is non-obvious over Pacetti 2 and Roby under 35 U.S.C. 103(a). Claims 9-11 and 54 depend from claim 8 and are non-obvious over Pacetti 2 and Roby under 35 U.S.C. 103(a) for at least the same reason.

c) Claims 12-18 and 55 are non-obvious over Pacetti 2 in view of Roby

Claim 12 defines coating composition for coating an implantable device. The composition comprises a poly(ester amide) (PEA) and a low surface energy, surface blooming polymer. The low surface energy, surface blooming polymer comprises a PEA miscible block or PEA miscible backbone. As discussed above, Pacetti 2 and Roby fail to teach or suggest such a coating composition. Claim 12 is thus non-obvious over Pacetti 2 and Roby under 35 U.S.C. 103(a). Claims 13-18 and 55 depend from

claim 12 and are non-obvious over Pacetti 2 and Roby under 35 U.S.C. 103(a) for at least the same reason.

d) Claims 19-22 and 56 are non-obvious over Pacetti 2 in view of Roby

Claim 19 defines a coating having a PEA polymer and at least one low surface energy polymer additive. The at least one low surface energy polymer additive comprises a PEA miscible block or PEA miscible backbone. As the above discussion shows, Pacetti 2 and Roby fail to teach or suggest such a coating. Therefore, claim 19 is thus non-obvious over Pacetti 2 and Roby under 35 U.S.C. 103(a). Claims 20-22 and 56 depend from claim 19 and are non-obvious over Pacetti 2 and Roby under 35 U.S.C. 103(a) for at least the same reason.

d) Claims 23-29, 34-38, 41, 42, 45-49, 51 and 57 are non-obvious over Pacetti 2 in view of Roby

Claim 23 defines an implantable device comprising a coating which comprises a poly(ester amide) (PEA) and a low surface energy, surface blooming polymer. The low surface energy, surface blooming polymer comprises a PEA miscible block or PEA miscible backbone. As the above discussion shows, Pacetti 2 and Roby fail to teach or suggest such an implantable device. Therefore, claim 23 is non-obvious over Pacetti 2 and Roby under 35 U.S.C. 103(a). Claims 24-29, 34-38, 41, 42, 45-49, 51 and 57 depend from claim 23 and are non-obvious over Pacetti 2 and Roby under 35 U.S.C. 103(a) for at least the same reason.

e) Claims 30-33,39, 40, 43, 44, 50, 52 and 58 are non-obvious over Pacetti 2 in view of Roby

Claim 30 defines an implantable device comprising a coating having a PEA polymer and at least one low surface energy polymer additive. The at least one low surface energy polymer additive comprises a PEA miscible block or PEA miscible backbone. For the reasons mentioned above, claim 30 is non-obvious over Pacetti 2 and Roby under 35 U.S.C. 103(a). Claims 31-33, 39, 40, 43, 44, 50, 52 and 58 depend from claim 30 and are non-obvious over Pacetti 2 and Roby under 35 U.S.C. 103(a) for at least the same reason.

CONCLUSION

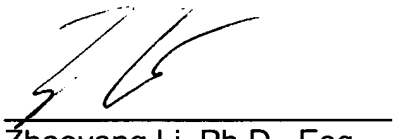
The examiner has failed, as a matter of law, to set forth a case of obviousness of claim 4 under 35 U.S.C. 103(a) over Roby in view of Pinhcuck.

The examiner has failed, as a matter of law, to set forth a case of obviousness of claims 1-3, 5-58 under 35 U.S.C. 103(a) over Pacetti 2 in view of Roby.

Appellants therefore respectfully request that the Board reverse the rejections and order the application to be passed to issue.

Date: March 3, 2008

Respectfully submitted,



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CLAIMS APPENDIX

WHAT IS CLAIMED:

1. (Previously presented) A method for forming a poly(ester amide) (PEA) coating with enhanced mechanical and release rate properties, comprising:

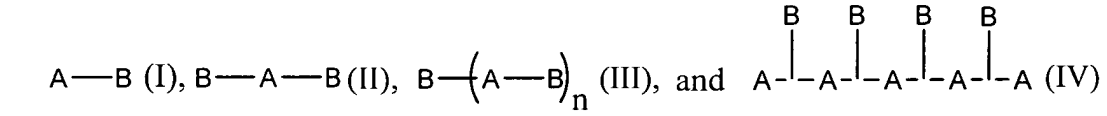
applying to an implantable device a solution or suspension of a composition comprising a PEA and a low surface energy, surface blooming polymer, and

forming a coating on the implantable device comprising PEA and the low surface energy, surface blooming polymer,

wherein the low surface energy, surface blooming polymer comprises a PEA miscible block or PEA miscible backbone.

2. (Previously presented) The method of claim 1 wherein the low surface energy, surface blooming polymer is selected from the group consisting of a block copolymer comprising a block miscible with the PEA and a hydrophobic block, a polymer comprising a backbone miscible with PEA and hydrophobic pendant groups, and a combination thereof.

3. (Original) The method of claim 1 wherein the low surface energy polymer is selected from the group consisting of formulae I-IV of the following structure:



A—B (I), B—A—B (II), B—(A—B)$_n$ (III), and A-(B)-A-(B)-A-(B)-A-(B)-A (IV)

wherein A is a PEA miscible block or PEA miscible backbone, and

wherein B is selected from the group consisting of a surface blooming block and a surface blooming pendant group.

4. (Previously presented) The method of claim 3 wherein A is selected from the group consisting of poly(ester-urea) urethane, polyglycol, poly(tetramethylene glycol), poly(propylene glycol), polycaprolactone, ethylene vinyl alcohol copolymer, poly(butyl methacrylate), poly(methacrylate), poly(acrylate), poly(ether-urethane), poly(ester-urethane), poly(carbonate-urethane), poly(silicone-urethane), poly(urea-urethane), poly(glycolide), poly(L-latide), poly(l-lactide-co-glycolide), poly(D,L-lactide), poly(D,L-lactide-co-glycolide), poly(D,L-lactide-co-L-lactide), poly(glycolide-co-caprolactone), poly(D,L-lactide-co-caprolactone), poly(L-lactide-co-caprolactone), poly(dioxanone), poly(trimethylene carbonate), poly(trimethylene carbonate) copolymers, poly(3-hydroxybutyrate), poly(3-hydroxyvalerate), poly(4-hydroxybutyrate), poly(3-

hydroxybutyrate-co-3-hydroxyvalerate), styrene-isobutylene-styrene triblock copolymer, poly(ethylene-co-vinyl acetate), and a combination thereof; and

wherein B is selected from the group consisting of a linear or branched alkyl chain, polysilanes, polysiloxanes, poly(dimethylsiloxane), a linear or branched perfluoro chain, and a combination thereof.

5. (Original) The method of claim 1 wherein the low surface energy polymer is selected from the group consisting of organosilicone surfactants, block copolymers of alkyl chains with polyglycol chains, fluoro surfactants, block copolymers of polydimethylsiloxane and polycaprolactone, polyurethanes end-capped with long chain perfluoro alcohols, poly(ester-urea)urethanes end-capped with long chain perfluoroalcohols, polyurethanes end-capped with alkyl chains, polyurethanes end-capped with polydimethylsiloxane, copolymers of polycaprolactone and fluoroalcohols, and combinations thereof.

6. (Original) The method of any of claims 1-5 wherein the composition further comprises a bioactive agent.

7. (Original) The method of claim 6 wherein the bioactive agent is selected from the group consisting of Everolimus, paclitaxel, docetaxel, estradiol, steroidal anti-inflammatory agents, antibiotics, anticancer agents, nitric oxide donors, super oxide dismutases, super oxide dismutases mimics, 4-amino-2,2,6,6-tetramethylpiperidine-1-oxyl (4-amino-TEMPO), ABT-578, tacrolimus, pimecrolimus, batimastat, mycophenolic acid, clobetasol, dexamethasone, rapamycin, 40-*O*-(3-hydroxy)propyl-rapamycin, 40-*O*-[2-(2-hydroxy)ethoxy]ethyl-rapamycin, or 40-*O*-tetrazole-rapamycin, antiproliferative agents, non-steroidal anti-inflammatory agents, immunosuppressive agents, antimigratory agents, and a combination thereof.

8. (Previously presented) A method for forming a poly(ester amide) (PEA) coating with enhanced mechanical and release rate properties, comprising:

applying to an implantable device a solution or suspension of a composition comprising a PEA and at least one low surface energy polymer additive, and

forming a coating on the implantable device comprising PEA and the at least one low surface energy polymer additive,

wherein the at least one low surface energy polymer additive comprises a PEA miscible block or PEA miscible backbone.

9. (Original) The method of claim 8 wherein the at least one low surface energy polymer additive is selected from the group consisting of Teflon (poly(tetrafluoroethylene), FEP (fluorinated ethylene-propylene), poly(tetrafluoroethylene-co-hexafluoropropene), PVDF (polyvinylidene fluoride), poly(fluoroalkenes), polysilanes, polysiloxanes, silicone (polydimethylsiloxane), hydrocarbon polymers, polyethylene, polypropylene, polystyrene, polybutadiene and combinations thereof.

10. (Original) The method of claims 8 or 9 wherein the composition further comprises a bioactive agent.

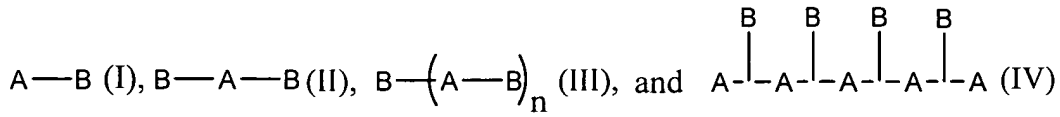
11. (Original) The method of claim 10 wherein the bioactive agent is selected from the group consisting of Everolimus, paclitaxel, docetaxel, estradiol, steroidal anti-inflammatory agents, antibiotics, anticancer agents, nitric oxide donors, super oxide dismutases, super oxide dismutases mimics, 4-amino-2,2,6,6-tetramethylpiperidine-1-oxyl (4-amino-TEMPO), ABT-578, tacrolimus, pimecrolimus, batimastat, mycophenolic acid, clobetasol, dexamethasone, rapamycin, 40-*O*-(3-hydroxy)propyl-rapamycin, 40-*O*-[2-(2-hydroxy)ethoxy]ethyl-rapamycin, or 40-*O*-tetrazole-rapamycin, antiproliferative agents, non-steroidal anti-inflammatory agents, immunosuppressive agents, antimigratory agents, and a combination thereof.

12. (Previously presented) A coating composition for coating an implantable device comprising a poly(ester amide) (PEA) and a low surface energy, surface blooming polymer,

wherein the low surface energy, surface blooming polymer comprises a PEA miscible block or PEA miscible backbone.

13. (Previously presented) The composition of claim 13 wherein the low surface energy, surface blooming polymer is selected from the group consisting of a block copolymer comprising a block miscible with the PEA and a hydrophobic block, a polymer comprising a backbone miscible with PEA and hydrophobic pendant groups, and a combination thereof.

14. (Original) The composition of claim 12 wherein the low surface energy, surface blooming polymer is selected from the group consisting of formulae I-IV of the following structure:



wherein A is a PEA miscible block or PEA miscible backbone, and

wherein B is selected from the group consisting of a surface blooming block and a surface blooming pendant group.

15. (Original) The composition of claim 14 wherein A is selected from the group consisting of polyurethane, poly(ester-urea) urethane, polyglycol, poly(tetramethylene glycol), poly(propylene glycol), polycaprolactone, ethylene vinyl alcohol copolymer, poly(butyl methacrylate), poly(methacrylate), poly(acrylate), and a combination thereof; and

wherein B is selected from the group consisting of a linear or branched alkyl chain, polysilanes, polysiloxanes, poly(dimethylsiloxane), a linear or branched perfluoro chain, and a combination thereof.

16. (Original) The composition of claim 15 wherein the low surface energy, surface blooming polymer is selected from the group consisting of organosilicone surfactants, block copolymers of alkyl chains with polyglycol chains, fluoro surfactants, block copolymers of polydimethylsiloxane and polycaprolactone, polyurethanes endcapped with long chain perfluoro alcohols, poly(ester-urea)urethanes endcapped with long chain perfluoro alcohols, polyurethanes endcapped with alkyl chains, polyurethanes endcapped with polydimethylsiloxane, and combinations thereof.

17. (Original) The composition of any of claims 12-16 further comprising a bioactive agent.

18. (Original) The composition of claim 17 wherein the bioactive agent is selected from the group consisting of Everolimus, paclitaxel, docetaxel, estradiol, steroidal anti-inflammatory agents, antibiotics, anticancer agents, nitric oxide donors, super oxide dismutases, super oxide dismutases mimics, 4-amino-2,2,6,6-tetramethylpiperidine-1-oxyl (4-amino-TEMPO), ABT-578, tacrolimus, pimecrolimus, batimastat, mycophenolic acid, clobetasol, dexamethasone, rapamycin, 40-*O*-(3-hydroxy)propyl-rapamycin, 40-*O*-[2-(2-hydroxy)ethoxy]ethyl-rapamycin, or 40-*O*-tetrazole-rapamycin, antiproliferative agents, non-steroidal anti-inflammatory agents, immunosuppressive agents, antimigratory agents, and a combination thereof.

19. (Previously presented) A coating composition for coating an implantable device comprising a poly(ester amide) (PEA) and at least one low surface energy polymer additive,

wherein the at least one low surface energy polymer additive comprises a PEA miscible block or PEA miscible backbone.

20. (Original) The composition of claim 19 wherein the at least one low surface energy polymer additive is selected from the group consisting of Teflon (poly(tetrafluoroethylene), FEP (fluorinated ethylene-propylene), poly(tetrafluoroethylene-co-hexafluoropropene), PVDF (polyvinylidene fluoride), poly(fluoroalkenes), polysilanes, polysiloxanes, silicone (polydimethylsiloxane), hydrocarbon polymers, polyethylene, polypropylene, polystyrene, polybutadiene and combinations thereof.

21. (Original) The composition of claims 19 or 20 further comprising a bioactive agent.

22. (Original) The composition of claim 21 wherein the bioactive agent is selected from the group consisting of Everolimus, paclitaxel, docetaxel, estradiol, steroidal anti-inflammatory agents, antibiotics, anticancer agents, nitric oxide donors, super oxide dismutases, super oxide dismutases mimics, 4-amino-2,2,6,6-tetramethylpiperidine-1-oxyl (4-amino-TEMPO), ABT-578, tacrolimus, pimecrolimus, batimastat, mycophenolic acid, clobetasol, dexamethasone, rapamycin, 40-*O*-(3-hydroxy)propyl-rapamycin, 40-*O*-[2-(2-hydroxy)ethoxy]ethyl-rapamycin, or 40-*O*-tetrazole-rapamycin, antiproliferative agents, non-steroidal anti-inflammatory agents, immunosuppressive agents, antimigratory agents, and a combination thereof.

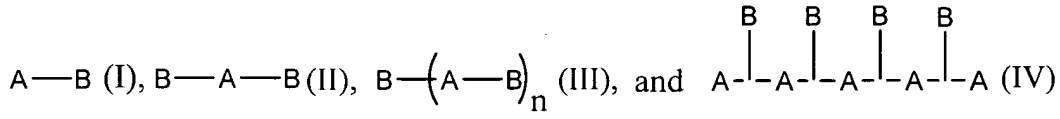
23. (Previously presented) An implantable device comprising a coating which comprises a poly(ester amide) (PEA) and a low surface energy, surface blooming polymer,

wherein the low surface energy, surface blooming polymer comprises a PEA miscible block or PEA miscible backbone.

24. (Previously presented) The implantable device of claim 23 wherein the low surface energy, surface blooming polymer is selected from the group consisting of a block copolymer comprising a block miscible with the PEA and a hydrophobic block, a

polymer comprising a backbone miscible with PEA and hydrophobic pendant groups, and a combination thereof.

25. (Original) The implantable device of claim 24 wherein the low surface energy, surface blooming polymer is selected from the group consisting of formulae I-IV of the following structure:



A—B (I), B—A—B (II), B—(A—B)$_n$ (III), and A-(B)-A-(B)-A-(B)-A-(B)-A (IV)

wherein A is a PEA miscible block or PEA miscible backbone, and

wherein B is selected from the group consisting of a surface blooming block and a surface blooming pendant group.

26. (Original) The implantable device of claim 25 wherein A is selected from the group consisting of polyurethane, poly(ester-urea) urethane, polyglycol, poly(tetramethylene glycol), poly(propylene glycol), polycaprolactone, ethylene vinyl alcohol copolymer, poly(butyl methacrylate), poly(methacrylate), poly(acrylate), and a combination thereof; and

wherein B is selected from the group consisting of a linear or branched alkyl chain, polysilanes, polysiloxanes, poly(dimethylsiloxane), a linear or branched perfluoro chain, and a combination thereof.

27. (Original) The implantable device of claim 26 wherein the low surface energy, surface blooming polymer is selected from the group consisting of organosilicone surfactants, block copolymers of alkyl chains with polyglycol chains, fluoro surfactants, block copolymers of polydimethylsiloxane and polycaprolactone, polyurethanes endcapped with long chain perfluoro alcohols, poly(ester-urea)urethanes endcapped with long chain perfluoro alcohols, polyurethanes endcapped with alkyl chains, polyurethanes endcapped with polydimethylsiloxane, and combinations thereof.

28. (Original) The implantable device of any of claims 23-27 further comprising a bioactive agent.

29. (Original) The implantable device of claim 28 wherein the bioactive agent is selected from the group consisting of Everolimus, paclitaxel, docetaxel, estradiol, steroidal anti-inflammatory agents, antibiotics, anticancer agents, nitric oxide donors, super oxide dismutases, super oxide dismutases mimics, 4-amino-2,2,6,6-

tetramethylpiperidine-1-oxyl (4-amino-TEMPO), ABT-578, tacrolimus, pimecrolimus, batimastat, mycophenolic acid, clobetasol, dexamethasone, rapamycin, 40-*O*-(3-hydroxy)propyl-rapamycin, 40-*O*-[2-(2-hydroxy)ethoxy]ethyl-rapamycin, or 40-*O*-tetrazole-rapamycin, antiproliferative agents, non-steroidal anti-inflammatory agents, immunosuppressive agents, antimigratory agents, and a combination thereof.

30. (Previously presented) An implantable device comprising a coating which comprises a poly(ester amide) (PEA) and at least one low surface energy polymer additive,

wherein the at least one low surface energy polymer additive comprises a PEA miscible block or PEA miscible backbone.

31. (Original) The implantable device of claim 30 wherein the at least one low surface energy polymer additive is selected from the group consisting of Teflon (poly(tetrafluoroethylene), FEP (fluorinated ethylene-propylene), poly(tetrafluoroethylene-co-hexafluoropropene), PVDF (polyvinylidene fluoride), poly(fluoroalkenes), polysilanes, polysiloxanes, silicone (polydimethylsiloxane), hydrocarbon polymers, polyethylene, polypropylene, polystyrene, polybutadiene and combinations thereof.

32. (Original) The implantable device of claims 30 or 31 further comprising a bioactive agent.

33. (Original) The implantable device of claim 32 wherein the bioactive agent is selected from the group consisting of Everolimus, paclitaxel, docetaxel, estradiol, steroidal anti-inflammatory agents, antibiotics, anticancer agents, nitric oxide donors, super oxide dismutases, super oxide dismutases mimics, 4-amino-2,2,6,6-tetramethylpiperidine-1-oxyl (4-amino-TEMPO), ABT-578, tacrolimus, pimecrolimus, batimastat, mycophenolic acid, clobetasol, dexamethasone, rapamycin, 40-*O*-(3-hydroxy)propyl-rapamycin, 40-*O*-[2-(2-hydroxy)ethoxy]ethyl-rapamycin, or 40-*O*-tetrazole-rapamycin, antiproliferative agents, non-steroidal anti-inflammatory agents, immunosuppressive agents, antimigratory agents, and a combination thereof.

34. (Original) The implantable device of claim 23 which is a stent.

35. (Original) The implantable device of claim 24 which is a stent.

36. (Original) The implantable device of claim 25 which is a stent.

37. (Original) The implantable device of claim 26 which is a stent.

38. (Original) The implantable device of claim 27 which is a stent.

39. (Original) The implantable device of claim 30 which is a stent.

40. (Original) The implantable device of claim 31 which is a stent.

41. (Original) The implantable device of claim 28 which is a drug-eluting stent.

42. (Original) The implantable device of claim 29 which is a drug-eluting stent.

43. (Original) The implantable device of claim 32 which is a drug-eluting stent.

44. (Original) The implantable device of claim 33 which is a drug-eluting stent.

45. (Original) A method of treating a disorder in a human being by implanting in the human being a stent as defined in claim 34,

wherein the disorder is selected from the group consisting of atherosclerosis, thrombosis, restenosis, hemorrhage, vascular dissection or perforation, vascular aneurysm, vulnerable plaque, chronic total occlusion, claudication, anastomotic proliferation for vein and artificial grafts, bile duct obstruction, ureter obstruction, tumor obstruction, and combinations thereof.

46. (Original) A method of treating a disorder in a human being by implanting in the human being a stent as defined in claim 35,

wherein the disorder is selected from the group consisting of atherosclerosis, thrombosis, restenosis, hemorrhage, vascular dissection or perforation, vascular aneurysm, vulnerable plaque, chronic total occlusion, claudication, anastomotic proliferation for vein and artificial grafts, bile duct obstruction, ureter obstruction, tumor obstruction, and combinations thereof.

47. (Original) A method of treating a disorder in a human being by implanting in the human being a stent as defined in claim 36,

wherein the disorder is selected from the group consisting of atherosclerosis, thrombosis, restenosis, hemorrhage, vascular dissection or perforation, vascular aneurysm, vulnerable plaque, chronic total occlusion, claudication, anastomotic proliferation for vein and artificial grafts, bile duct obstruction, ureter obstruction, tumor obstruction, and combinations thereof.

48. (Original) A method of treating a disorder in a human being by implanting in the human being a stent as defined in claim 37,

wherein the disorder is selected from the group consisting of atherosclerosis, thrombosis, restenosis, hemorrhage, vascular dissection or perforation, vascular

aneurysm, vulnerable plaque, chronic total occlusion, claudication, anastomotic proliferation for vein and artificial grafts, bile duct obstruction, ureter obstruction, tumor obstruction, and combinations thereof.

49. (Original) A method of treating a disorder in a human being by implanting in the human being a stent as defined in claim 38,

wherein the disorder is selected from the group consisting of atherosclerosis, thrombosis, restenosis, hemorrhage, vascular dissection or perforation, vascular aneurysm, vulnerable plaque, chronic total occlusion, claudication, anastomotic proliferation for vein and artificial grafts, bile duct obstruction, ureter obstruction, tumor obstruction, and combinations thereof.

50. (Original) A method of treating a disorder in a human being by implanting in the human being a stent as defined in claim 39,

wherein the disorder is selected from the group consisting of atherosclerosis, thrombosis, restenosis, hemorrhage, vascular dissection or perforation, vascular aneurysm, vulnerable plaque, chronic total occlusion, claudication, anastomotic proliferation for vein and artificial grafts, bile duct obstruction, ureter obstruction, tumor obstruction, and combinations thereof.

51. (Original) A method of treating a disorder in a human being by implanting in the human being a stent as defined in claim 42,

wherein the disorder is selected from the group consisting of atherosclerosis, thrombosis, restenosis, hemorrhage, vascular dissection or perforation, vascular aneurysm, vulnerable plaque, chronic total occlusion, claudication, anastomotic proliferation for vein and artificial grafts, bile duct obstruction, ureter obstruction, tumor obstruction, and combinations thereof.

52. (Original) A method of treating a disorder in a human being by implanting in the human being a stent as defined in claim 44,

wherein the disorder is selected from the group consisting of atherosclerosis, thrombosis, restenosis, hemorrhage, vascular dissection or perforation, vascular aneurysm, vulnerable plaque, chronic total occlusion, claudication, anastomotic proliferation for vein and artificial grafts, bile duct obstruction, ureter obstruction, tumor obstruction, and combinations thereof.

53. (Previously presented) The method of claim 1, wherein the coating is biologically benign.

54. (Previously presented) The method of claim 8, wherein the coating is biologically benign.

55. (Previously presented) The coating of claim 12, which is biologically benign.

56. (Previously presented) The coating of claim 19, which is biologically benign.

57. (Previously presented) The implantable device of claim 23, wherein the coating is biologically benign.

58. (Previously presented) The implantable device of claim 30, wherein the coating is biologically benign.

EVIDENCE APPENDIX

Attached hereto are the following:

(A) Office action mailed August 1, 2006;

(B) U.S. patent application publication No. 20050149173 by Hunter et al. ("Hunter");

(C) U.S. patent application publication No. 20020123801 by Pacetti et al. ("Pacetti");

(D) Response to Office Action filed on November 1, 2006;

(E) Final Office Action mailed on December 27, 2006;

(F) WO 03/022323 by Pacetti ("Pacetti 2");

(G) WO 98/32398 by Roby et al. ("Roby");

(H) Response to Office Action filed on February 12, 2007;

(I) Advisory Action mailed on March 16, 2007;

(J) Response to Advisory Action and a Request for Continued Examination mailed on March 22, 2007;

(K) Office Action mailed on June 12, 2007;

(L) Response to Office Action filed on September 12, 2007;

(M) Final Office Action mailed on October 10, 2007;

(N) U.S. patent application publication No. 2002/0107330 by Pinhcuck et al. ("Pinhcuck");

(O) Response to Final Office Action filed on January 7, 2008;

(P) Notice of Appeal filed on January 7, 2008; and

(Q) Advisory Action mailed on January 30, 2008;

RELATED PROCEEDINGS APPENDIX

There are no related proceedings.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,139	06/03/2004	Jessica R. DesNoyer	50623.326	2159

7590 08/01/2006

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DOCKETED: due 11/1/06

AUG 11 2006

BY: tjb Atty: PL

SQUIRE, SANDERS & DEMPSEY

EXAMINER	
ROGERS, JAMES WILLIAM	
ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 08/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/750,139	DESNOYER ET AL.	
	Examiner	Art Unit	
	James W. Rogers, Ph.D.	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 June 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *08/01/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2,13 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims all recite the limitation "wherin the hydrophobic block has a δ value lower than that of PEA". The symbol δ is considered indefinite by the examiner because δ is used in countless mathematical, physics and chemical equations defining a variable, although adequately defined in the specification it is suggested that the applicants define δ within the claims so it is no longer indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 8-11,19-22,30-33,39,43,44,50 and 52 are rejected under 35 U.S.C. 102(e) as being anticipated by Hunter et al. (US 20050149173 A1, received benefit of provisional applications filling date of 11/20/2003).

Hunter teaches covered stents which can be coated by fibrosis-enhancing agents comprising PEA, the coating can contain other polymers for use in conjunction with the fibrosing agent including polysilanes (meeting the limitation of a low energy polymer additive), the coating can further comprise bio-active agents such as anti-inflammatory and immunoresponsive agents. See abstract, [0019], [0017],[0207],[0413] and [0415]. The stents covered in the Hunter patent could be used to treat vascular aneurysm, restenosis, ect, therefore the limitations in claims 50 and 52 are met.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunter et al. (US 20050149173 A1, received benefit of provisional application filling date

of 11/20/2003) as applied to claims 8-11,19-22,30-33,39,43,44,50 and 52 above, and further in view of Pacetti et al. (US 2002/0123801)

Hunter is disclosed above. The Hunter patent while disclosing the use of a low surface energy polymer does not reasonable disclose a low surface energy surface blooming polymer.

Pacetti discloses a stent having a diffusion barrier for controlled delivery of a bioactive substance, the barrier can be a polyurethane having a non-polar soft segment which includes hydrocarbons, silicones, fluorosilicones or combinations thereof. See [0017].

It would have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to combine the art described in the documents above because Hunter discloses all that is encompassed within applicants claimed invention except for a low surface energy surface blooming polymer, while the Pacetti patent is used to show that low energy surface blooming polymers such as polyurethanes with a silicone soft segment were well known at the time of the invention. The motivation to combine the above documents would be a coated stent, the coating comprised of PEA and a low surface energy blooming polymer, the coating capable of delivering an active ingredient. Thus, the claimed invention, taken as a whole was *prima facie* obvious over the combined teachings of the prior art.

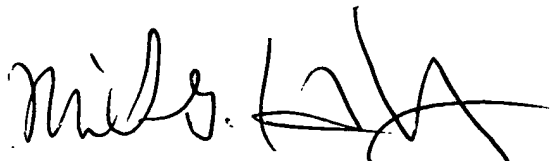
Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D.

whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER

FORM PTO-1449 (Modified) U.S. DEPARTMENT OF COMMERCE
US Patent and Trademark Office

INFORMATION DISCLOSURE CITATION in an Application

(Use several sheets if necessary)

Docket No.	Application No.
50623.326	10/750,139
Applicant	
DesNoyer et al.	
Filing Date	**Group Art Unit**
June 3, 2004	1755

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Examiner Initial	Ref. No.	Document Number	Date of Patent	Name	Class	Subclass	Filing Date If Appropriate
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Non compliant
filling date is not required

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	B3	EP 1 023 879	8/2/00	EPO				
	B4	EP 1 192 957	4/3/02	EPO				
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Non compliant filing date not required

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	B8	WO 03/082368	10/9/03	PCT				
	B9	WO 04/000383	12/31/03	PCT				
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EXAMINER	DATE CONSIDERED 7/14/2006

EXAMINER: Initial if references considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Notice of References Cited	Application/Control No. 10/750,139	Applicant(s)/Patent Under Reexamination DESNOYER ET AL.	
	Examiner James W. Rogers, Ph.D.	Art Unit 1618	Page 1 of 1

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*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-2005/0149173 A1	07-2005	Hunter et al.	623/001.42
*	B	US-2002/0123801 A1	09-2002	Pacetti et al.	623/1.46
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
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FOREIGN PATENT DOCUMENTS

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	N					
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NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
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Date Mailed: October , 2006	By: ZL/rmk	Docket No.: 50623.326
Serial No.: 10/750,139		Filed: June 3, 2004
Applicants: Jessica R. DesNoyer, Syed F.A. Hossainy, Stephen D. Pacetti, Yiwen Tang		
Title: Poly(Ester Amide) Coating Composition For Implantable Devices		

The following has been received in the U.S. Patent Office on the date stamped hereon:

- ☒ Deposit Account Authorization 07-1850
- ☒ Transmittal Form (1 page)
- ☒ Certificate of Mailing
- ☐ Formal Drawings ___ sheets
- ☐ Fee Transmittal (in duplicate)
- ☐ Petition For Extension of Time
- ☐ Assignment & Recordation Cover Sheet (in duplicate)
- ☒ Response to Office Action (18 pages)
- ☒ Express Mail No.: EV 721161206 US
- ☐ Terminal Disclaimer (1 page)
- ☒ Amendment Transmittal (1 page) (in duplicate)
- ☐ Oath/Declaration/Power of Attorney
- ☐ Information Disclosure Statement with Form PTO-1449 and copies of ___References
- ☒ Other: Declaration Under 37 CFR 1.131 (5 pages); Appendix A (7 pages)

#196278

SANFRANCISCO/196278.1

Date Mailed: October , 2006	By: ZL/rmk	Docket No.: 50623.326
Serial No.: 10/750,139		Filed: June 3, 2004
Applicants: Jessica R. DesNoyer, Syed F.A. Hossainy, Stephen D. Pacetti, Yiwen Tang		
Title: Poly(Ester Amide) Coating Composition For Implantable Devices		

The following has been received in the U.S. Patent Office on the date stamped hereon:

- ☒ Deposit Account Authorization 07-1850
- ☒ Transmittal Form (1 page)
- ☒ Certificate of Mailing
- ☐ Formal Drawings ___ sheets
- ☐ Fee Transmittal (in duplicate)
- ☐ Petition For Extension of Time
- ☐ Assignment & Recordation Cover Sheet (in duplicate)
- ☒ Response to Office Action (18 pages)
- ☒ Express Mail No.: EV 721161206 US
- ☐ Terminal Disclaimer (1 page)
- ☒ Amendment Transmittal (1 page) (in duplicate)
- ☐ Oath/Declaration/Power of Attorney
- ☐ Information Disclosure Statement with Form PTO-1449 and copies of ___References
- ☒ Other: Declaration Under 37 CFR 1.131 (5 pages); Appendix A (7 pages)

#196278

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Please type a plus sign (+) inside this box → [+]

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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission	33

Application Number	10/750,139
Filing Date	June 3, 2004
First Named Inventor	Jessica R. DesNoyer
Group Art Unit	1618
Examiner Name	James William Rogers
Attorney Docket Number	50623.326

ENCLOSURES *(check all that apply)*

- ☒ Deposit Account 07-1850 Authorization
- ☒ Postage Paid Return Postcard
- ☒ Amendment and Response to Office Action (18 pages)
- ☒ Amendment Transmittal Letter (1 page) (in duplicate)
- ☐ Affidavits/declaration(s)
- ☐ Petition for Extension of Time (__ month) (1 page) (in duplicate)
- ☐ Information Disclosure Statement with Form PTO-1449 citing ___ References
- ☒ Express Mail Label No. EV 721161206 US
- ☐ Certified Copy of Priority Document(s)
- ☐ Response to Missing Parts/ Incomplete Application
  - ☐ Response to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Assignment Papers *(for an Application)*
- ☐ Drawing(s) Formal __ Sheets with Submission of Formal
- ☐ Issue Fee Transmittal with PTO-85b (in duplicate)
- ☐ Request for Continued Examination Transmittal (RCE)
- ☐ Fee Transmittal Form (in duplicate)
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer (1 page)
- ☐ Statement of Common Ownership
- ☐ CD, Number of CD(s) ____
- ☐ After Allowance Communication to Group
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to Group *(Appeal Notice, Brief, Reply Brief)*
- ☐ Proprietary Information
- ☐ Request for Status of Application
- ☒ Other Enclosure(s) *(please identify below)*:
  Declaration Under 37 CFR 1.131 (5 pages); Appendix A (7 pages)

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	Squire, Sanders & Dempsey L.L.P. Zhaoyang Li, Ph.D., Reg. No. 46,872
Signature	
Date	November 1, 2006

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this date:

Typed or printed name	Rebecca M. Klits		
Signature	Rebecca M. Klits	Date	11/1/06

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be send to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231 DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

EV721161206US

Express Mail Label No. EV 72116120[redacted]S

AMENDMENT TRANSMITTAL LETTER (Large Entity)			Docket No.
Applicant(s): Jessica R. DesNoyer et al.			50623.326
Serial No.	Filing Date	Examiner	Group Art Unit
10/750,139	June 3, 2004	James William Rogers	1618

Invention:

Poly(Ester Amide) Coating Composition For Implantable Devices

TO THE COMMISSIONER FOR PATENTS:

Transmitted herewith is an amendment in the above-identified application.

The fee has been calculated and is transmitted as show below.

CLAIMS AS AMENDED

	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST # PREV. PAID FOR	NUMBER EXTRA CLAIMS PRESENT	RATE	ADDITIONAL FEE
TOTAL CLAIMS	73	67	6	X $50.00	$300.00
INDEP. CLAIMS	6	6	0	X $200.00	$00.00
Multiple Dependent Claims (check if applicable) ☐					$00.00
				TOTAL ADDITIONAL FEE FOR THIS AMENDMENT	$300.00

☐ No additional fee is required for amendment.

☒ Please charge Deposit Account No. **07-1850** in the amount of **$300.00**

A duplicate copy of this sheet is enclosed.

☐ A check in the amount of _____ to cover the filing fee is enclosed.

☒ The Commissioner is hereby authorized to charge payment of any necessary fees associated with this communication or credit any overpayment to Deposit Account No. **07-1850.**

A duplicate copy of this sheet is enclosed.

☐ Any additional filing fees required under 37 C.F.R. 1.16.

☐ Any patent application processing fees under 37 C.F.R. 1.17.

Dated: November 1, 2006

Squire, Sanders & Dempsey L.L.P.
1 Maritime Plaza, Suite 300
San Francisco, CA 94111
(415) 954-0200

Zhaoyang Li, Ph.D.
Reg. No. 46,872

cc: Docket:

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	DesNoyer et al.	Examiner:	James William Rogers
Serial No.:	10/750,139	Art Unit:	1618
Filed:	June 3, 2004		

Title: Poly(Ester Amide) Coating Composition For Implantable Devices

Mail Stop: Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

DECLARATION UNDER 37 CFR § 1.131

We, Jessica R. DesNoyer, Syed F.A. Hossainy, Stephen D. Pacetti, and Yiwen Tang declare as follows:

1. The application identified above was granted the filing date of June 3, 2004.

2. We conceived of or invented the subject matter of the application identified above in the United States prior to November 10, 2003. See Appendix A – redacted invention disclosure form.

3. We further declare that all statements made herein of our own knowledge are true and that all statements made upon information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the

United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Executed at Santa Clara, California on this 2nd day of October, 2006.

By: Jessica R. DesNoyer
Jessica R. DesNoyer

Executed at Fremont, California on this _____ day of _____, 2006.

By: _____
Syed F.A. Hossainy

Executed at San Jose, California on this _____ day of _____, 2006.

By: _____
Stephen D. Pacetti

Executed at San Jose, California on this _____ day of _____, 2006.

By: _____
Yiwen Tang

United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Executed at Santa Clara, California on this _____ day of _____, 2006.

By:_____
Jessica R. DesNoyer

Executed at Fremont, California on this _____ day of _____, 2006.

By:_____
Syed F.A. Hossainy

Executed at San Jose, California on this _____ day of _____, 2006.

By:_____
Stephen D. Pacetti

Executed at San Jose, California on this _____ day of _____, 2006.

By:_____
Yiwen Tang

United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Executed at Santa Clara, California on this _____ day of _____, 2006.

By:_____
Jessica R. DesNoyer

Executed at Fremont, California on this _____ day of _____, 2006.

By:_____
Syed F.A. Hossainy

Executed at San Jose, California on this 26th day of Sept., 2006.

By: Stephen Pacetti
Stephen D. Pacetti

Executed at San Jose, California on this _____ day of _____, 2006.

By:_____
Yiwen Tang

United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Executed at Santa Clara, California on this _____ day of _____, 2006.

By:_____
Jessica R. DesNoyer

Executed at Fremont, California on this _____ day of _____, 2006.

By:_____
Syed F.A. Hossainy

Executed at San Jose, California on this _____ day of _____, 2006.

By:_____
Stephen D. Pacetti

Executed at San Jose, California on this 4th day of April, 2006.

By:_____
Yiwen Tang

APPENDIX A

GUIDANT CONFIDENTIAL & PRIVILEGED

For Legal Department Use Only
Docket No.: 4135
Date Assigned: 5/14/03
Date Discl. Rec'd: MAY 13 2003

INVENTION DISCLOSURE FORM

ADVANCED CARDIOVASCULAR SYSTEMS, INC.

This is a form for disclosing ideas and inventions to the Guidant Legal Department for patent consideration. This form may be used before experimental work has been done. While some of the requested information may not be available at this time, include as much information as you can about the invention. Attach additional sheets if necessary, and sign and date each sheet. Additional information will be requested later.

Please complete each indicated area and return to Intellectual Property Paralegal, Guidant Vascular Intervention Group, 3200 Lakeside Drive, Santa Clara, CA 95052, and a copy to the R&D Director.

1. **DESCRIPTIVE TITLE OF THE INVENTION:** Poly (Ester Amide) (PEA)/Low Surface Energy Polymer Blends for Release Rate Control and Mechanical Property Enhancement

KEY WORDS: Stent, Drug delivery, PEA, Shear, Stent delivery

2. Submitter(s): *(please provide your full name, including middle name)*

Inventor 1			
Full Name: **Jessica Reneé DesNoyer**	Signature: Jessica Renée DesNoyer		
Home address: **1610 Nantucket Circle #315**	City: **Santa Clara**	State: **CA**	Zip **95054**
Citizenship: **USA**	Home phone no.: **408-980-8654**		
Work no.: **408-845-3189**	Work fax no.: **408-845-3689**		
Empl. No. **028572**	Division Name: **DES Strategic Unit**	Manager Name: **Bob McGreevy**	

Inventor 2			
Full Name: **Syed Faiyaz Ahmed Hossainy**	Signature:		
Home address: **34325 Tupelo St.**	City: **Fremont**	State: **CA**	Zip **94555**
Citizenship: **Bangladeshi**	Home phone no.: **510-797-8683**		
Work no.: **408-845-3948**	Work fax no.: **408-845-3689**		
Empl. No. **020780**	Division Name: **DES Strategic Unit**	Manager Name: **Jose Calle**	

Inventor 3			
Full Name: **Stephen Dirk Pacetti**	Signature: Stephen Pacetti		
Home address: **4578 Madoc Way**	City: **San Jose**	State: **CA**	Zip **95130**
Citizenship: **USA**	Home phone no.: **408-370-1496**		
Work no.: **408-845-3452**	Work fax no.: **408-845-3689**		
Empl. No. **017953**	Division Name: **DES Strategic Unit**	Manager Name: **Murthy Simhambhatla**	

Inventor 4			
Full Name: **Eveleen Tang**	**Signature:**		
Home address: **#223, 1230 San Tomas Aquino Rd.**	City: **San Jose**	State: **CA**	Zip: **95117**
Citizenship: **Canada**	Home phone no.: **408 260 6888**		
Work no.: **408 845 1716**	Work fax no.: **408 845 3689**		
Empl. No. **027598**	Division Name: **DES**	Manager Name: **Gene Park**	

Inventors initials:
1 JD 2 SH 3 S.S. 4 MT 5____ 6____ 7____ 8____ 9____

3. Invention Applicability/Project/Release/Sale Information
To which division or operation does this invention best apply? Stent
Field of Technology: Drug Delivery Stent
Related Invention Disclosure Docket Nos.: TBD
Project Name/Description: Drug Delivery Stent
Product Name: TBD
Estimated/actual manufacturing release date of invention or product incorporating or using the invention: TBD (date)
Estimated/actual date of offer for sale of product incorporating or using the invention: TBD (date)

4. DESCRIPTION AND USE

(a) Describe the invention in as much detail as possible, and include a description of a working prototype, if any. Write your description using reference numerals placed on a drawing. Point out and explain relationship with associated equipment. (b) How is the invention used? (c) How does it relate to present or potential commercial products of the company or others? (d) State the significance of the invention, and any problems it is intended to solve. Please supplement when possible by attaching sketches, engineering drawings, pages from lab books, photographs, and the like.

INTRODUCTION

Poly (Ester Amide) (PEA) currently is being investigated within Guidant as a bioabsorbable drug eluting stent coating. PEA has some very promising attributes, such as excellent biocompatibility in a 28-day porcine model and the ability to control the release of everolimus.

Generally, polymers with poor mechanical integrity are ruled out as potential DES coatings early on.

The fact that PEA already has demonstrated excellent biocompatibility *in vivo* and that it is the only bioabsorbable polymer in our portfolio able to control drug release makes it too valuable a material to rule out.

Inventors initials:
1 [illegible] 2 SA 3 [illegible] 4 [illegible] 5____ 6____ 7____ 8____ 9____

As an example, Fig. 1 shows a scanning electron micrograph of a PEA Benzyl Ester coated Vision stent depicting the typical type of mechanical failure observed upon deployment. In this example, the stent was crimped and icy hot processed onto a Vision catheter, e-beam sterilized, and then expanded to 16 atm in the simulated use apparatus.

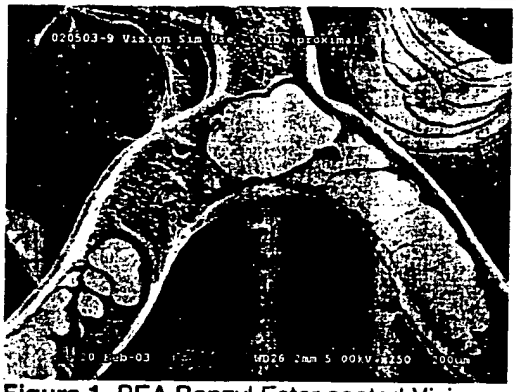


Figure 1. PEA Benzyl Ester coated Vision post-simulated use showing mechanical failure due to balloon shear.

Since the mechanical failures exhibited by PEA coated stents originate from the adhesive properties of the polymer, which cause the stent to stick to the catheter balloon, decreasing or eliminating the adhesive interaction between the PEA coating and the balloon should result in enhanced mechanical properties.

(a) **DISCLOSURE**

What is disclosed is a method for improving the mechanical and release rate properties of PEA by blending it with low surface energy, surface blooming polymers. The concept is to formulate a coating solution comprised of PEA, a spray solvent, and a low surface energy polymer. During the spray coating process, the low surface energy polymer will reside substantially at the air/liquid interface of the spray droplet. As the solvent evaporates, the coating surface becomes enriched in the low surface energy polymer, and the PEA component is pushed into the coating interior, thus preventing an interaction between PEA and the catheter balloon. The end result is a PEA-based coating with enhanced mechanical integrity.

Additionally, the low surface energy polymer can function to retard drug release from the PEA matrix by creating a hydrophobic barrier at the coating surface. This means that thinner coatings can be used to obtain the same release rate control. Incorporating a hydrophobic surface bloomer into the PEA matrix will have the added effect of altering the polymer degradation rate. As the hydrophobicity of the PEA blend is increased, the degradation rate will decrease, a desirable outcome since rapid degradation can promote inflammation. The hydrophobic surface bloomer does not need to be incorporated into all coating layers. For example, it could be added to only the to coat layer.

Inventors initials:
1 2 3 4 5 6 7 8 9

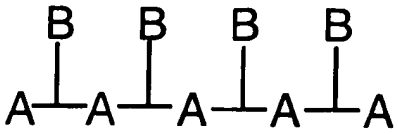
The hydrophobic surface blooming component could be a low surface energy polymer additive or it could be a block copolymer with a PEA miscible block and a hydrophobic surface modifier block. Since PEA is a bioabsorbable polymer, only other bioabsorbable polymers should be incorporated into the blend. Polymers that could function as hydrophobic surface modifiers include silwet surfactants, block copolymers of alkyl chains with polyglycol chains, Fluorad surfactants, block copolymers of polydimethylsiloxane and polycaprolactone, polyurethanes endcapped with long chain perfluoro alcohols, poly(ester-urea)urethanes encapped with long chain perfluoro alcohols, polyurethanes endcapped with alkyl chains, and polyurethanes endcapped with polydimethylsiloxane. These surface blooming components can come in several configurations. One is a simple AB block copolymer where the A block is polymer miscible and the B block is the hydrophobic and surface blooming.

A—B

Another configuration is where the polymer is of BAB type where the surface blooming groups are at either end.

B—A—B

Still another arrangement is where the polymer miscible backbone "A" has surface blooming groups B grafted to it along its length.



To generalize, the polymer segment "A" is intended to be polymer miscible to keep the surface blooming additive in the coating. It can be a polyurethane, poly(ester-urea)urethane, polygycol such as poly(tetramethylene glycol) or poly(propylene glycol), polycaprolactone, EVAL, poly(butyl methacrylate), poly(methacrylate), or poly(acrylate). Group "B' can be selected from a linear or branched alkyl chain, poly(dimethylsiloxane), or a linear or branched perfluoro chain.

The objective is to create a PEA-based DES coating with enhanced mechanical and release rate properties.

(b) HOW IS THE INVENTION USED?

The focus of the invention lies in the area of DES coating formulation. Blending PEA with a hydrophobic surface blooming polymer will give a DES coating with acceptable mechanical integrity and release rate control. Once the hydrophobic surface modifier is chosen, the formulation will be coated using our current spray coating process.

Inventors initials:
1 CRD 2 SH 3 L.P. 4 [illegible] 5____ 6____ 7____ 8____ 9____

5. PROJECTED GENERIC SCOPE

Describe the invention in terms of the ***broadest*** generic scope which you expect will be operable (e.g. if a machine or article, describe alternate type and sizes of materials for construction, etc.; if a process, describe alternate manufacturing conditions, etc.).

A formulation where a low surface energy polymer is incorporated into the coating for the purpose of improving mechanical and release rate properties could be used on any drug eluting stent. Such coatings can be used on balloon expandable or self-expanding stents. This stent may be utilized in any part of the vasculature including neurological, carotid, coronary, renal, aortic, iliac, femoral, or other peripheral vasculature. There is no inherent limitation on the length, diameter, strut pattern, or strut thickness.

6.

Has a literature search been made? Yes_____ No __X____ Don't know_____

If "Yes", list and if possible, attach copies of all literature, publications, patents and applications of which are relating to the invention. See section in Guidelines for Completing Invention Disclosure Form concerning obligation of disclosure.

Is this invention an improvement of an existing company product? Yes__X___ No _____ Don't know_____

If "Yes" identify the product: _Endoluminal Stents____

List the closest known prior art/technology: _Stents____

Inventors initials:
1 GD 2 SF 3 AP 4 ____ 5____ 6____ 7____ 8____ 9____

7. Publication of the Invention

What is the current stage of development of the invention? Concept

Has a description been published or is it scheduled to be published? Yes_____ No __X___ Don't know_____
Has a description been disclosed or is it scheduled to be disclosed outside of Guidant?
Yes_____No __X____Don't know_____

If "Yes", when and to whom? _____

Was a Non-Disclosure Agreement used? Yes_____No _____Don't know_____

If "Yes", please attach a copy of the agreement to the disclosure.

8. Joint Development of Development Contract

Was this invention made under a government agency contract? Yes_____No __X____Don't know_____

If "Yes":
- List all non-Guidant inventors: _____
- List all government contract numbers: _____

9. Witness Signature (not a submitter)

Read and understood the completed Invention Disclosure Form

Steve Dugan
Printed Name

Signature 5/13/03
Date

Inventors initials:
1 JKD 2 SH 3 S.P. 4 [illegible] 5____ 6____ 7____ 8____ 9____

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	DesNoyer et al.	Examiner:	James William Rogers
Serial No.:	10/750,139	Art Unit:	1618
Filed:	June 3, 2004		

Title: Poly(Ester Amide) Coating Composition For Implantable Devices

Mail Stop: Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

RESPONSE AND AMENDMENT TO OFFICE ACTION

Dear Examiner Rogers:

This communication responds to the Office Action mailed on August 1, 2006. Accompanying this communication is a 1.131 declaration.

In the claims

1. (Original) A method for forming a poly(ester amide) (PEA) coating with enhanced mechanical and release rate properties, comprising:

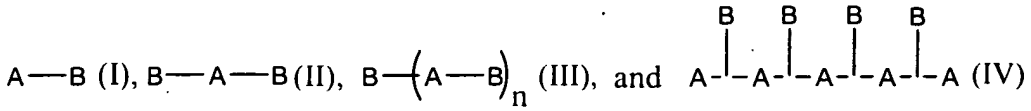
applying to an implantable device a solution or suspension of a composition comprising PEA and a low surface energy, surface blooming polymer, and

forming a coating on the implantable device comprising PEA and the low surface energy, surface blooming polymer.

2. (Currently amended) The method of claim 1 wherein the low surface energy, surface blooming polymer is selected from the group consisting of a block copolymer comprising a block miscible with the PEA and a hydrophobic block, a polymer comprising a backbone miscible with PEA and hydrophobic pendant groups, and a combination thereof~~,~~

~~wherein the hydrophobic block has a δ value below than that of PEA~~.

3. (Original) The method of claim 1 wherein the low surface energy polymer is selected from the group consisting of formulae I-IV of the following structure:



wherein A is a PEA miscible block or PEA miscible backbone, and

wherein B is selected from the group consisting of a surface blooming block and a surface blooming pendant group.

4. (Original) The method of claim 3 wherein A is selected from the group consisting of polyurethane, poly(ester-urea) urethane, polyglycol, poly(tetramethylene glycol), poly(propylene glycol), polycaprolactone, ethylene vinyl alcohol copolymer, poly(butyl methacrylate), poly(methacrylate), poly(acrylate), poly(ether-urethane), poly(ester-urethane), poly(carbonate-urethane), poly(silicone-urethane), poly(urea-urethane), poly(glycolide), poly(L-latide), poly(l-lactide-co-glycolide), poly(D,L-lactide), poly(D,L-lactide-co-glycolide), poly(D,L-lactide-co-L-lactide), poly(glycolide-co-caprolactone), poly(D,L-lactide-co-caprolactone), poly(L-lactide-co-caprolactone), poly(dioxanone), poly(trimethylene carbonate), poly(trimethylene carbonate) copolymers, poly(3-hydroxybutyrate), poly(3-hydroxyvalerate), poly(4-hydroxybutyrate), poly(3-hydroxybutyrate-co-3-hydroxyvalerate), styrene-butadiene-styrene block copolymer, styrene-butylene/ethylene-styrene block copolymer, styrene-isobutylene-styrene triblock copolymer, poly(ethylene-co-vinyl acetate), and a combination thereof; and

wherein B is selected from the group consisting of a linear or branched alkyl chain, polysilanes, polysiloxanes, poly(dimethylsiloxane), a linear or branched perfluoro chain, and a combination thereof.

5. (Original) The method of claim 1 wherein the low surface energy polymer is selected from the group consisting of organosilicone surfactants, block copolymers of alkyl chains with polyglycol chains, fluoro surfactants, block copolymers of polydimethylsiloxane and polycaprolactone, polyurethanes end-capped with long chain perfluoro alcohols, poly(ester-urea)urethanes end-capped with long chain perfluoroalcohols, polyurethanes end-capped with

alkyl chains, polyurethanes end-capped with polydimethylsiloxane, copolymers of polycaprolactone and fluoroalcohols, and combinations thereof.

6. (Original) The method of any of claims 1-5 wherein the composition further comprises a bioactive agent.

7. (Original) The method of claim 6 wherein the bioactive agent is selected from the group consisting of Everolimus, paclitaxel, docetaxel, estradiol, steroidal anti-inflammatory agents, antibiotics, anticancer agents, nitric oxide donors, super oxide dismutases, super oxide dismutases mimics, 4-amino-2,2,6,6-tetramethylpiperidine-1-oxyl (4-amino-TEMPO), ABT-578, tacrolimus, pimecrolimus, batimastat, mycophenolic acid, clobetasol, dexamethasone, rapamycin, 40-*O*-(3-hydroxy)propyl-rapamycin, 40-*O*-[2-(2-hydroxy)ethoxy]ethyl-rapamycin, or 40-*O*-tetrazole-rapamycin, antiproliferative agents, non-steroidal anti-inflammatory agents, immunosuppressive agents, antimigratory agents, and a combination thereof.

8. (Original) A method for forming a poly(ester amide) (PEA) coating with enhanced mechanical and release rate properties, comprising:

applying to an implantable device a solution or suspension of a composition comprising PEA and at least one low surface energy polymer additive, and

forming a coating on the implantable device comprising PEA and the at least one low surface energy polymer additive.

9. (Original) The method of claim 8 wherein the at least one low surface energy polymer additive is selected from the group consisting of Teflon (poly(tetrafluoroethylene), FEP (fluorinated ethylene-propylene), poly(tetrafluoroethylene-co-hexafluoropropene), PVDF (polyvinylidene fluoride), poly(fluoroalkenes), polysilanes, polysiloxanes, silicone

(polydimethylsiloxane), hydrocarbon polymers, polyethylene, polypropylene, polystyrene, polybutadiene and combinations thereof.

10. (Original) The method of claims 8 or 9 wherein the composition further comprises a bioactive agent.

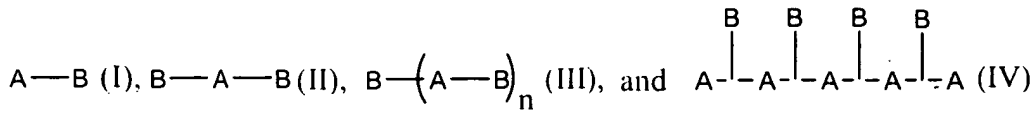
11. (Original) The method of claim 10 wherein the bioactive agent is selected from the group consisting of Everolimus, paclitaxel, docetaxel, estradiol, steroidal anti-inflammatory agents, antibiotics, anticancer agents, nitric oxide donors, super oxide dismutases, super oxide dismutases mimics, 4-amino-2,2,6,6-tetramethylpiperidine-1-oxyl (4-amino-TEMPO), ABT-578, tacrolimus, pimecrolimus, batimastat, mycophenolic acid, clobetasol, dexamethasone, rapamycin, 40-*O*-(3-hydroxy)propyl-rapamycin, 40-*O*-[2-(2-hydroxy)ethoxy]ethyl-rapamycin, or 40-*O*-tetrazole-rapamycin, antiproliferative agents, non-steroidal anti-inflammatory agents, immunosuppressive agents, antimigratory agents, and a combination thereof.

12. (Original) A coating composition for coating an implantable device comprising poly(ester amide) (PEA) and a low surface energy, surface blooming polymer.

13. (Currently amended) The composition of claim 13 wherein the low surface energy, surface blooming polymer is selected from the group consisting of a block copolymer comprising a block miscible with the PEA and a hydrophobic block, a polymer comprising a backbone miscible with PEA and hydrophobic pendant groups, and a combination thereof;

~~wherein the hydrophobic block has a ô value below than that of PEA~~.

14. (Original) The composition of claim 12 wherein the low surface energy, surface blooming polymer is selected from the group consisting of formulae I-IV of the following structure:



wherein A is a PEA miscible block or PEA miscible backbone, and

wherein B is selected from the group consisting of a surface blooming block and a surface blooming pendant group.

15. (Original) The composition of claim 14 wherein A is selected from the group consisting of polyurethane, poly(ester-urea) urethane, polyglycol, poly(tetramethylene glycol), poly(propylene glycol), polycaprolactone, ethylene vinyl alcohol copolymer, poly(butyl methacrylate), poly(methacrylate), poly(acrylate), and a combination thereof; and

wherein B is selected from the group consisting of a linear or branched alkyl chain, polysilanes, polysiloxanes, poly(dimethylsiloxane), a linear or branched perfluoro chain, and a combination thereof.

16. (Original) The composition of claim 15 wherein the low surface energy, surface blooming polymer is selected from the group consisting of organosilicone surfactants, block copolymers of alkyl chains with polyglycol chains, fluoro surfactants, block copolymers of polydimethylsiloxane and polycaprolactone, polyurethanes endcapped with long chain perfluoro alcohols, poly(ester-urea)urethanes endcapped with long chain perfluoro alcohols, polyurethanes endcapped with alkyl chains, polyurethanes endcapped with polydimethylsiloxane, and combinations thereof.

17. (Original) The composition of any of claims 12-16 further comprising a bioactive agent.

18. (Original) The composition of claim 17 wherein the bioactive agent is selected from the group consisting of Everolimus, paclitaxel, docetaxel, estradiol, steroidal anti-inflammatory agents, antibiotics, anticancer agents, nitric oxide donors, super oxide dismutases, super oxide dismutases mimics, 4-amino-2,2,6,6-tetramethylpiperidine-1-oxyl (4-amino-TEMPO), ABT-578, tacrolimus, pimecrolimus, batimastat, mycophenolic acid, clobetasol, dexamethasone, rapamycin, 40-*O*-(3-hydroxy)propyl-rapamycin, 40-*O*-[2-(2-hydroxy)ethoxy]ethyl-rapamycin, or 40-*O*-tetrazole-rapamycin, antiproliferative agents, non-steroidal anti-inflammatory agents, immunosuppressive agents, antimigratory agents, and a combination thereof.

19. (Original) A coating composition for coating an implantable device comprising poly(ester amide) (PEA) and at least one low surface energy polymer additive.

20. (Original) The composition of claim 19 wherein the at least one low surface energy polymer additive is selected from the group consisting of Teflon (poly(tetrafluoroethylene), FEP (fluorinated ethylene-propylene), poly(tetrafluoroethylene-co-hexafluoropropene), PVDF (polyvinylidene fluoride), poly(fluoroalkenes), polysilanes, polysiloxanes, silicone (polydimethylsiloxane), hydrocarbon polymers, polyethylene, polypropylene, polystyrene, polybutadiene and combinations thereof.

21. (Original) The composition of claims 19 or 20 further comprising a bioactive agent.

22. (Original) The composition of claim 21 wherein the bioactive agent is selected from the group consisting of Everolimus, paclitaxel, docetaxel, estradiol, steroidal anti-inflammatory agents, antibiotics, anticancer agents, nitric oxide donors, super oxide dismutases,

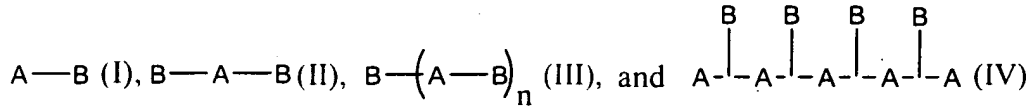
super oxide dismutases mimics, 4-amino-2,2,6,6-tetramethylpiperidine-1-oxyl (4-amino-TEMPO), ABT-578, tacrolimus, pimecrolimus, batimastat, mycophenolic acid, clobetasol, dexamethasone, rapamycin, 40-*O*-(3-hydroxy)propyl-rapamycin, 40-*O*-[2-(2-hydroxy)ethoxy]ethyl-rapamycin, or 40-*O*-tetrazole-rapamycin, antiproliferative agents, non-steroidal anti-inflammatory agents, immunosuppressive agents, antimigratory agents, and a combination thereof.

23. (Original) An implantable device comprising a coating which comprises a poly(ester amide) (PEA) and a low surface energy, surface blooming polymer.

24. (Currently amended) The implantable device of claim 23 wherein the low surface energy, surface blooming polymer is selected from the group consisting of a block copolymer comprising a block miscible with the PEA and a hydrophobic block, a polymer comprising a backbone miscible with PEA and hydrophobic pendant groups, and a combination thereof~~,~~

~~wherein the hydrophobic block has a δ value below than that of PEA~~.

25. (Original) The implantable device of claim 24 wherein the low surface energy, surface blooming polymer is selected from the group consisting of formulae I-IV of the following structure:



wherein A is a PEA miscible block or PEA miscible backbone, and

wherein B is selected from the group consisting of a surface blooming block and a surface blooming pendant group.

26. (Original) The implantable device of claim 25 wherein A is selected from the group consisting of polyurethane, poly(ester-urea) urethane, polyglycol, poly(tetramethylene glycol), poly(propylene glycol), polycaprolactone, ethylene vinyl alcohol copolymer, poly(butyl methacrylate), poly(methacrylate), poly(acrylate), and a combination thereof; and

wherein B is selected from the group consisting of a linear or branched alkyl chain, polysilanes, polysiloxanes, poly(dimethylsiloxane), a linear or branched perfluoro chain, and a combination thereof.

27. (Original) The implantable device of claim 26 wherein the low surface energy, surface blooming polymer is selected from the group consisting of organosilicone surfactants, block copolymers of alkyl chains with polyglycol chains, fluoro surfactants, block copolymers of polydimethylsiloxane and polycaprolactone, polyurethanes endcapped with long chain perfluoro alcohols, poly(ester-urea)urethanes endcapped with long chain perfluoro alcohols, polyurethanes endcapped with alkyl chains, polyurethanes endcapped with polydimethylsiloxane, and combinations thereof.

28. (Original) The implantable device of any of claims 23-27 further comprising a bioactive agent.

29. (Original) The implantable device of claim 28 wherein the bioactive agent is selected from the group consisting of Everolimus, paclitaxel, docetaxel, estradiol, steroidal anti-inflammatory agents, antibiotics, anticancer agents, nitric oxide donors, super oxide dismutases, super oxide dismutases mimics, 4-amino-2,2,6,6-tetramethylpiperidine-1-oxyl (4-amino-TEMPO), ABT-578, tacrolimus, pimecrolimus, batimastat, mycophenolic acid, clobetasol, dexamethasone, rapamycin, 40-*O*-(3-hydroxy)propyl-rapamycin, 40-*O*-[2-(2-

hydroxy)ethoxy]ethyl-rapamycin, or 40-*O*-tetrazole-rapamycin, antiproliferative agents, non-steroidal anti-inflammatory agents, immunosuppressive agents, antimigratory agents, and a combination thereof.

30. (Original) An implantable device comprising a coating which comprises poly(ester amide) (PEA) and at least one low surface energy polymer additive.

31. (Original) The implantable device of claim 30 wherein the at least one low surface energy polymer additive is selected from the group consisting of Teflon (poly(tetrafluoroethylene), FEP (fluorinated ethylene-propylene), poly(tetrafluoroethylene-co-hexafluoropropene), PVDF (polyvinylidene fluoride), poly(fluoroalkenes), polysilanes, polysiloxanes, silicone (polydimethylsiloxane), hydrocarbon polymers, polyethylene, polypropylene, polystyrene, polybutadiene and combinations thereof.

32. (Original) The implantable device of claims 30 or 31 further comprising a bioactive agent.

33. (Original) The implantable device of claim 32 wherein the bioactive agent is selected from the group consisting of Everolimus, paclitaxel, docetaxel, estradiol, steroidal anti-inflammatory agents, antibiotics, anticancer agents, nitric oxide donors, super oxide dismutases, super oxide dismutases mimics, 4-amino-2,2,6,6-tetramethylpiperidine-1-oxyl (4-amino-TEMPO), ABT-578, tacrolimus, pimecrolimus, batimastat, mycophenolic acid, clobetasol, dexamethasone, rapamycin, 40-*O*-(3-hydroxy)propyl-rapamycin, 40-*O*-[2-(2-hydroxy)ethoxy]ethyl-rapamycin, or 40-*O*-tetrazole-rapamycin, antiproliferative agents, non-steroidal anti-inflammatory agents, immunosuppressive agents, antimigratory agents, and a combination thereof.

34. (Original) The implantable device of claim 23 which is a stent.

35. (Original) The implantable device of claim 24 which is a stent.

36. (Original) The implantable device of claim 25 which is a stent.

37. (Original) The implantable device of claim 26 which is a stent.

38. (Original) The implantable device of claim 27 which is a stent.

39. (Original) The implantable device of claim 30 which is a stent.

40. (Original) The implantable device of claim 31 which is a stent.

41. (Original) The implantable device of claim 28 which is a drug-eluting stent.

42. (Original) The implantable device of claim 29 which is a drug-eluting stent.

43. (Original) The implantable device of claim 32 which is a drug-eluting stent.

44. (Original) The implantable device of claim 33 which is a drug-eluting stent.

45. (Original) A method of treating a disorder in a human being by implanting in the human being a stent as defined in claim 34,

wherein the disorder is selected from the group consisting of atherosclerosis, thrombosis, restenosis, hemorrhage, vascular dissection or perforation, vascular aneurysm, vulnerable plaque, chronic total occlusion, claudication, anastomotic proliferation for vein and artificial grafts, bile duct obstruction, ureter obstruction, tumor obstruction, and combinations thereof.

46. (Original) A method of treating a disorder in a human being by implanting in the human being a stent as defined in claim 35,

wherein the disorder is selected from the group consisting of atherosclerosis, thrombosis, restenosis, hemorrhage, vascular dissection or perforation, vascular aneurysm, vulnerable plaque, chronic total occlusion, claudication, anastomotic proliferation for vein and artificial grafts, bile duct obstruction, ureter obstruction, tumor obstruction, and combinations thereof.

47. (Original) A method of treating a disorder in a human being by implanting in the human being a stent as defined in claim 36,

wherein the disorder is selected from the group consisting of atherosclerosis, thrombosis, restenosis, hemorrhage, vascular dissection or perforation, vascular aneurysm, vulnerable plaque, chronic total occlusion, claudication, anastomotic proliferation for vein and artificial grafts, bile duct obstruction, ureter obstruction, tumor obstruction, and combinations thereof.

48. (Original) A method of treating a disorder in a human being by implanting in the human being a stent as defined in claim 37,

wherein the disorder is selected from the group consisting of atherosclerosis, thrombosis, restenosis, hemorrhage, vascular dissection or perforation, vascular aneurysm, vulnerable plaque, chronic total occlusion, claudication, anastomotic proliferation for vein and artificial grafts, bile duct obstruction, ureter obstruction, tumor obstruction, and combinations thereof.

49. (Original) A method of treating a disorder in a human being by implanting in the human being a stent as defined in claim 38,

wherein the disorder is selected from the group consisting of atherosclerosis, thrombosis, restenosis, hemorrhage, vascular dissection or perforation, vascular aneurysm, vulnerable plaque, chronic total occlusion, claudication, anastomotic proliferation for vein and artificial grafts, bile duct obstruction, ureter obstruction, tumor obstruction, and combinations thereof.

50. (Original) A method of treating a disorder in a human being by implanting in the human being a stent as defined in claim 39,

wherein the disorder is selected from the group consisting of atherosclerosis, thrombosis, restenosis, hemorrhage, vascular dissection or perforation, vascular aneurysm, vulnerable plaque, chronic total occlusion, claudication, anastomotic proliferation for vein and artificial grafts, bile duct obstruction, ureter obstruction, tumor obstruction, and combinations thereof.

51. (Original) A method of treating a disorder in a human being by implanting in the human being a stent as defined in claim 42,

wherein the disorder is selected from the group consisting of atherosclerosis, thrombosis, restenosis, hemorrhage, vascular dissection or perforation, vascular aneurysm, vulnerable plaque, chronic total occlusion, claudication, anastomotic proliferation for vein and artificial grafts, bile duct obstruction, ureter obstruction, tumor obstruction, and combinations thereof.

52. (Original) A method of treating a disorder in a human being by implanting in the human being a stent as defined in claim 44,

wherein the disorder is selected from the group consisting of atherosclerosis, thrombosis, restenosis, hemorrhage, vascular dissection or perforation, vascular aneurysm, vulnerable plaque, chronic total occlusion, claudication, anastomotic proliferation for vein and artificial grafts, bile duct obstruction, ureter obstruction, tumor obstruction, and combinations thereof.

53. (New) The method of claim 1, wherein the coating is biologically benign.

54. (New) The method of claim 8, wherein the coating is biologically benign.

55. (New) The coating of claim 12, which is biologically benign.

56. (New) The coating of claim 19, which is biologically benign.

57. (New) The implantable device of claim 23, wherein the coating is biologically benign.

58. (New) The implantable device of claim 30, wherein the coating is biologically benign.

Remarks

Claims 1-52 are pending. Claims 1-52 have been rejected. Claims 53-58 have been newly added.

Information Disclosure Statement

The Examiner crossed out the U.S. application references on page 3, middle through most of page 5 of the Information Disclosure Statement (IDS) filed on July 27, 2005, as being non-compliant. The Examiner alleged this part of the IDS improperly lists the filing dates of the co-pending applications because they are not required to be listed in the IDS. Applicants respectfully direct the Examiner to 37 CFR 1.98(b)(3), which specifically requires that a U.S. application must be identified by the **inventor, application number, and filing date** (see also MPEP §609). Applicants therefore respectfully request the Examiner to consider the crossed out U.S. application references.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 2, 13, and 24 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Applicants believe the amendments to claims moot these rejections.

Rejections under 35 U.S.C. § 102

Claims 8-11, 19-22, 30-33, 39, 43, 44, 50 and 52 are rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. application No. 20050149173 by Hunter et al. Applicants believe the 1.131 declaration submitted herewith renders Hunter non-prior art and therefore the rejections are moot.

For the newly added claims 53-58, all of them recite **a coating having a poly(ester amide) (PEA) polymer and at least one low surface energy polymer is biologically benign**.

In contrast, Hunter describes an intravascular device having a polymer material **that induces fibrosis between the device and the host tissue** when the device is implanted in an animal.

Rejections under 35 U.S.C. § 103

Claims 1-52 are rejected under 35 U.S.C. §103(a) as being unpatentable over Hunter in view of U.S. application No. 2002/0123801 by Pacetti et al. ("Pacetti").

As mentioned above, Hunter no longer qualifies as prior art. Pacetti describes a coating that includes a polyurethane having a non-polar soft segment that can include hydrocarbons, silicones, fluorosilicones or combinations thereof.

Claim 1 defines a method of forming a coating having a poly(ester amide) (PEA) polymer and a low surface energy, surface blooming polymer, which Pacetti fails to describe or teach. Therefore, claim 1 is patentably allowable over Pacetti. Claims 2-7 depend from claim 1 and are patentable over Pacetti for at least the same reason.

Claim 8 defines a method of forming a coating having a PEA polymer and at least one low surface energy polymer additive. Pacetti fails to describe or teach this element. Therefore, claim 8 is patentably allowable over Pacetti. Claims 9-11 depend from claim 8 and are patentable over Pacetti for at least the same reason.

Claim 12 defines a coating having a PEA polymer and at least one low surface energy polymer. Pacetti fails to describe or teach this element. Therefore, claim 12 is patentably allowable over Pacetti. Claims 13-18 depend from claim 12 and are patentable over Pacetti for at least the same reason.

Claim 19 defines a coating having a PEA polymer and at least one low surface energy polymer additive. Pacetti fails to describe or teach this element. Therefore, claim 19 is

patentably allowable over Pacetti. Claims 20-22 depend from claim 19 and are patentable over Pacetti for at least the same reason.

Claim 23 defines a medical device comprising a coating having a PEA polymer and at least one low surface energy polymer. Pacetti fails to describe or teach this element. Therefore, claim 23 is patentably allowable over Pacetti. Claims 24-29, 34-38, 41, 42, 45-49 and 51 depend from claim 23 and are patentable over Pacetti for at least the same reason.

Claim 30 defines a medical device comprising a coating having a PEA polymer and at least one low surface energy polymer additive. Pacetti fails to describe or teach this element. Therefore, claim 30 is patentably allowable over Pacetti. Claims 31-33, 39, 40, 43, 44, 50 and 52 depend from claim 30 and are patentable over Pacetti for at least the same reason.

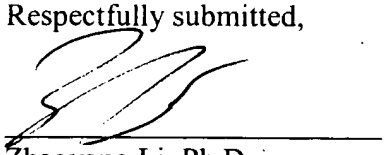
The undersigned authorizes the examiner to charge any fees that may be required or credit of any overpayment to be made to Deposit Account No. 07-1850.

Withdrawal of the rejection and allowance of the claims are respectfully requested. **If the Examiner has any suggestions or amendments to the claims to place the claims in condition for allowance, applicant would prefer a telephone call to the undersigned attorney for approval of an Examiner's amendment.** If the Examiner has any questions or concerns, the Examiner is invited to telephone the undersigned attorney at (415) 393-9885.

Date: November 1, 2006

Squire, Sanders & Dempsey L.L.P.
One Maritime Plaza, Suite 300
San Francisco, CA 94111
Telephone (415) 393-9885
Facsimile (415) 393-9887

Respectfully submitted,



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,139	06/03/2004	Jessica R. DesNoyer	50623.326	2159

7590 12/27/2006

Squire, Sanders & Dempsey, L.L.P.
Suite 300
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FINAL OFFICE ACTION
RESPONSE DUE: 3/27/07
NTC of APPEAL DUE: 6/27/07

EXAMINER	
ROGERS, JAMES WILLIAM	
ART UNIT	**PAPER NUMBER**
1618	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/27/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

DOCKETED: FINAL REJECTION

JAN 03 2007

BY: tjb Atty: PJ

SQUIRE, SANDERS & DEMPSEY

Office Action Summary	Application No.	Applicant(s)	
	10/750,139	DESNOYER ET AL.	
	Examiner	Art Unit	
	James W. Rogers, Ph.D.	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/06/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

DECLARATION UNDER 37 CFR § 1.131

Applicant's declaration filed 11/01/2006 has been fully considered and has now rendered the 102(e) rejection and 103(a) rejection in the last office action filed 08/01/2006 moot because the Hunter et al. reference (US 20050149173 A1) no longer qualifies as prior art due to the disclosure within that the inventors conceived of their invention before November 10th 2003. Therefore all of the prior art rejections (35 USC 102(e) and 103(a)) have been withdrawn. The examiner has also withdrawn the 35 USC 112 second paragraph rejections because the currently amended claims renders the rejections moot.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti (WO 03/022323 A1, cited by applicants in IDS filed 11/06/2006) and in view of Roby et al. (WO 98/32398 A1, cited by applicant in IDS filed 11/06/2006). This new ground of rejection was necessitated both by amendment (new claims 53-58) and by applicants newly disclosed IDS filed 11/06/2006.

Pacetti discloses a coating for reducing the rate release of drugs from stents in which the stent includes a polymer capable of maintaining its crystalline lattice structure while the therapeutic agent is released from the stent. See abstract. The polymers include polyurethanes with a polydimethylsiloxane soft segments, poly(vinylidene fluoride-co-methacrylic acid) ect. See [0020]-[0021] and claims 11,16-17. The therapeutic agents included anti proliferative-substances, antibiotics, paclitaxel ect. See [0028]. Regarding the limitation that the implantable device is applied to a solution of PEA and a low surface energy, surface blooming polymer, Pacetti discloses that the composition can be applied by any conventional method including spraying the composition on the device or by immersing the device in the composition. See [0023]. Regarding claims 45-52 Pacetti discloses several methods of using the coated stents including treatment of obstructions caused by tumors and for treating occluded regions of blood vessels caused by abnormal or inappropriate migration and proliferation of smooth muscle tissue cells, thrombosis and restenosis. See [0032].

Pacetti does not disclose the use of PEA in combination with the crystalline polymers (same as low surface energy polymer or low surface energy, surface blooming polymer), to produce a coating containing a therapeutic for a stent.

Roby discloses the preparation of polyesteramides and surgical devices fabricated from them. See abstract and pag 1 lin 1-21. Roby is used mostly for the disclosure within that polyesteramides can be used as a coating for surgical devices and the polyesteramide surgical devices could also incorporate therapeutic agents such as antimicrobial agents. See pag 6 lin 3-pag 8 lin 18. The polyesteramide compositions could also be blended with other absorbable or non-absorbable compositions. Roby disclosed that the advantages or significance of PEA for use in medical devices was the susceptibility of their ester linkages to hydrolyze, conferring upon PEA the ability to be absorbed or resorbed by the body and the amide linkages confer upon them desirable mechanical properties. Regarding claims 53-58 it is obvious that since both the coatings described in Pacetti and Roby are used for medical devices for use in the body the coating would be biologically benign and since the combination of the coatings described in the references above are the same as applicants claimed invention it is also obvious that the coatings would have the same properties, including biological properties.

It would have been prime facie obvious to a person of ordinary skill in the art at the time the claimed invention was made to combine the art described in the documents above because Pacetti disclosed the use of both the same low surface energy polymers and low surface energy, surface blooming polymers for a stent coating containing a

therapeutic as applicants claims while Roby disclosed that coatings for surgical devices containing PEA and therapeutics was already well known in the art at the time of the invention. The motivation to combine the above documents would be to produce and use a coated stent in which the coating comprised a therapeutic, PEA and a highly crystalline hydrophobic polymer (same as applicants low surface energy polymer). The advantage of such a coating would be that the combination would provide a biologically absorbable coating with desirable mechanical properties from the PEA polymer disclosed in Roby and a controlled release of the therapeutic from the crystalline polymers disclosed in Pacetti. Thus, the claimed invention, taken as a whole was *prima facie* obvious over the combined teachings of the prior art.

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER

FORM PTO-1449 (Modified)	US DEPARTMENT OF COMMERCE	Docket No.	Application No.
Approved for use through 10/31/2002	US Patent and Trademark Office	50623.326	10/750,139
INFORMATION DISCLOSURE CITATION in an Application (Use several sheets if necessary)		Applicant: Jessica Renee DesNoyer et al.	
		Filing Date: June 3, 2004	Group Art Unit: 1618

U.S. PATENT DOCUMENTS

Examiner Initial	Ref. No.	Document Number	Date of Patent	Name	Class	Subclass	Filing Date if Appropriate
	A1	2,386,454	10/9/45	Frosch et al.			
	A2	3,773,737	11/20/73	Goodman et al.			
	A3	3,849,514	11/19/74	Gray, Jr. et al.			
	A4	4,226,243	10/7/80	Shalaby et al.			
	A5	4,329,383	5/11/82	Joh			
	A6	4,343,931	8/10/82	Barrows			
	A7	4,529,792	7/16/85	Barrows			
	A8	4,611,051	9/9/86	Hayes et al.			
	A9	4,656,242	4/7/87	Swan et al.			
	A10	4,733,665	3/29/88	Palmaz			
	A11	4,800,882	1/31/89	Gianturco			
	A12	4,882,168	11/21/89	Casey et al.			
	A13	4,886,062	12/12/89	Wiktor			
	A14	4,941,870	7/17/90	Okada et al.			
	A15	4,977,901	12/18/90	Ofstead			
	A16	5,100,992	3/31/92	Cohn et al.			
	A17	5,112,457	5/12/92	Marchant			
	A18	5,133,742	7/28/92	Pinchuk			
	A19	5,165,919	11/24/92	Sasaki et al.			
	A20	5,219,980	6/15/93	Swidler			
	A21	5,272,012	12/21/93	Opolski			
	A22	5,292,516	3/8/94	Viegas et al.			
	A23	5,298,260	3/29/94	Viegas et al.			
	A24	5,300,295	4/5/94	Viegas et al.			
	A25	5,306,501	4/26/94	Viegas et al.			

11/19/2006

	A26	5,306,786	4/26/94	Moens et al.			
	A27	5,328,471	7/12/94	Slepian			
	A28	5,330,768	7/19/94	Park et al.			
	A29	5,380,299	1/10/95	Fearnot et al.			
	A30	5,417,981	5/23/95	Endo et al.			
	A31	5,447,724	9/5/95	Helmus et al.			
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(54) Title: COATING FOR REDUCING THE RATE OF RELEASE OF DRUGS FROM STENTS

(57) Abstract: A stent for delivery of a therapeutic agent is disclosed. The stent includes a polymer coating for reducing the rate of release of the therapeutic agent. The polymer has a crystalline structure wherein the polymer is capable of significantly maintaining the crystalline lattice structure while the therapeutic agent is released from the stent such that the aqueous environment to which the stent is exposed subsequent to the implantation of the stent does not significantly convert the crystalline lattice structure of the polymer to an amorphous structure.

COATING FOR REDUCING THE RATE OF RELEASE OF DRUGS FROM STENTS

BACKGROUND OF THE INVENTION

Field of the Invention

[0001] A medical device, such as a stent, for delivering a therapeutic substance is disclosed. The stent includes a polymeric coating for reducing the rate of release of the therapeutic substance.

Description of the Background

[0002] Blood vessel occlusions are commonly treated by mechanically enhancing blood flow in the affected vessels, such as by employing a stent. Stents act as scaffoldings, functioning to physically hold open and, if desired, to expand the wall of the passageway. Typically stents are capable of being compressed, so that they can be inserted through small lumens via catheters, and then expanded to a larger diameter once they are at the desired location. Examples in the patent literature disclosing stents include U.S. Patent No. 4,733,665 issued to Palmaz, U.S. Patent No. 4,800,882 issued to Gianturco, and U.S. Patent No. 4,886,062 issued to Wiktor.

[0003] Stents are used not only for mechanical intervention but also as vehicles for providing biological therapy. Biological therapy can be achieved by medicating the stents. Medicated stents provide for the local administration of a therapeutic substance at the diseased site. Local delivery of a therapeutic substance is a preferred method of treatment because the substance is concentrated at a specific

site and thus smaller total levels of medication can be administered in comparison to systemic dosages that often produce adverse or even toxic side effects for the patient.

[0004] One method of medicating a stent involves the use of a polymeric carrier coated onto the surface of the stent. A composition including a solvent, a polymer dissolved in the solvent, and a therapeutic substance dispersed in the blend is applied to the stent by immersing the stent in the composition or by spraying the composition onto the stent. The solvent is allowed to evaporate, leaving on the stent strut surfaces a coating of the polymer and the therapeutic substance impregnated in the polymer.

[0005] Depending on the physiological mechanism targeted, the therapeutic substance may be required to be released at an efficacious concentration for an extended duration of time. Increasing the quantity of the therapeutic substance in the polymeric coating can lead to poor coating mechanical properties, inadequate coating adhesion, and overly rapid rate of release. Increasing the quantity of the polymeric compound by producing a thicker coating can perturb the geometrical and mechanical functionality of the stent as well as limit the procedures for which the stent can be used.

[0006] It is desirable to increase the residence time of a substance at the site of implantation, at a therapeutically useful concentration, without the addition of a greater percentage of the therapeutic substance to the polymeric coating and without the application of a significantly thicker coating.

SUMMARY OF THE INVENTION

[0007] The present invention discloses a stent for delivery of a therapeutic agent. The stent includes a polymer coating for reducing the rate of release of the therapeutic agent. The polymer has a crystalline lattice structure, wherein the polymer is capable of significantly maintaining the crystalline lattice structure while the therapeutic agent is released from the stent such that the aqueous environment to which the stent is exposed subsequent to the implantation of the stent does not significantly convert the crystalline lattice structure of the polymer to an amorphous structure.

[0008] The coating can contain the therapeutic agent. In one embodiment, the melting point of the polymer is greater than or equal to about 135°C at ambient pressure. In another embodiment, the polymer is a hydrophobic polymer having a solubility parameter not greater than about 10.7 $(cal/cm^3)^{1/2}$.

[0009] Also disclosed is a method of forming a coating for a stent. The method includes applying a first composition including a polymeric material to at least a portion of the stent to form a polymer coating supported by the stent. The polymer has a crystalline structure, wherein the aqueous environment to which the coating is exposed subsequent to the implantation of the stent does not significantly convert the crystalline structure of the polymer to an amorphous structure for the duration of time which the agent is released from the stent.

[0010] The present invention additionally discloses a composition for coating a stent. The composition includes a fluid and a polymer dissolved in the fluid. The

polymer includes a crystalline structure during the duration of delivery of an active agent from the stent, and the aqueous environment to which the stent is exposed subsequent to the implantation procedure does not significantly change the crystalline structure to an amorphous structure.

[0011] Also disclosed is a stent for delivering a therapeutic agent to an implanted site. The stent includes a radially expandable body structure and a polymeric coating supported by the body structure for extending the residence time of the therapeutic agent at the implanted site. The polymeric coating is made from a hydrophobic polymer having a degree of crystallinity that remains at or above about 10% at least until a significant amount of the therapeutic substance has been released from the stent.

DETAILED DESCRIPTION

Embodiments of the Rate-Reducing Coating

[0012] One mechanism through which the release rate of an active agent from a medical device can be controlled is the crystallinity of the polymer with which the medical device is coated. A polymer in which the molecules are arranged in a highly ordered and regular pattern formed by folding and stacking of the polymer chains is said to be crystalline. By contrast, amorphous polymers have molecules that are arranged randomly with no regularity of orientation with respect to one another. Among the factors that affect polymer crystallinity are the stereoregularity of the polymer, the tacticity of the polymer, the presence of branching, the degree

of polymerization, and the strength of the intermolecular forces between the polymer chains.

[0013] The structural arrangement and regularity of a polymer is an important factor in the determination of polymer crystallinity. A regular arrangement along the polymer chains provides the polymer structure with a high degree of symmetry, allowing the chains to pack into crystals. Irregularity along the polymer chains, however, prevents the chains from packing closely to one another, thereby decreasing crystallinity. Polymers with regular, linear, and rigid structures tend to form ordered crystals. By contrast, polymers with large side groups, mixed tacticity or an atactic structure, a mix of side or functional groups, or composed of more than one monomer tend not to pack well into crystalline structures.

[0014] The degree of polymerization also contributes to the determination of the crystallinity of a polymer. Relatively short chains organize themselves into crystalline structures more readily than longer molecules, as longer molecules tend to become tangled and thus have difficulty arranging themselves in an ordered manner, resulting in a more amorphous structure.

[0015] Also influencing polymer crystallinity is the presence of intermolecular forces. The presence of polar and hydrogen bonding groups favors crystallinity because such groups promote dipole-dipole and hydrogen bonding intermolecular forces. Such strong interchain forces hold the polymer chains in a tightly packed configuration, thereby promoting crystallinity. By contrast, polymers with little or

no intermolecular forces will tend to have random, non-crystalline structures as a result of thermal motion.

[0016] Typically, as the crystallinity of a polymer increases, so too does the polymer's ability to reduce the rate at which an active agent is released from a medical device coated with the polymer. This is because it is more difficult for an active agent to diffuse through a tightly packed, crystalline polymer than a more loosely packed, amorphous polymer. The purpose of the coating of the present invention is to decrease the rate of release of an active agent therefrom. Accordingly, the polymer for forming the rate-reducing coating should be selected to have sufficient crystallinity such that the active agent may not readily diffuse therethrough.

[0017] The degree of crystallinity of the polymer can be measured by the amount of the polymer that is in the form of crystallites or a detectable pattern of crystals as may be observed using conventional techniques such as x-ray diffraction, measurement of specific volume, infrared spectroscopy, and thermal analysis. For use with the embodiments of the present invention, the polymer can have a crystallinity of not less than about 10%, alternatively not less than about 25%. In accordance with another embodiment the degree of crystallinity should not be less than about 50%. When exposed to an aqueous environment such as blood, the polymer can have a crystallinity of not less than about 10%, alternativley not less than 25%. In one example, the polymer can have a crystallinity of at least 50% or at least 25% in an aqueous environment, such as in contact with blood.

[0018] In addition, the crystalline polymers for use in the rate-reducing coating of the present invention should be capable of maintaining their crystallinity in the aqueous *in vivo* environment in which the coated medical device will be employed. The crystallinity of some polymers decreases when exposed to water. This is due to absorption of water by the polymer, which is also known as polymer swelling. The absorbed water can reduce or eliminate the polymer crystallinity. In extreme cases, such absorption can lead to complete dissolution of the polymer. Polymers that contain ionic, polar, or hydrogen bonding groups have the potential to absorb water. In general, if the interaction of the polymer with water is stronger than that of the polymer with itself or of water with itself, the polymer will swell with water. When a polymer swells, its chains move apart to form pores in the polymeric network, thereby increasing the diffusion rate of an active agent through the polymeric network. Accordingly, the polymers for use in the rate-reducing coating of the present invention should be selected to maintain their crystallinity, and thus their rate-reducing capabilities, in an aqueous environment.

[0019] Many crystalline polymers that are hydrophobic can maintain their crystallinity in an aqueous environment because hydrophobic materials are "water-avoiding." One method of defining the hydrophobicity of a polymer is by the solubility parameter of the polymer, also known as the polymer's cohesive energy density. The solubility parameter is represented by Equation 1:

$$\delta = (\Delta E/V)^{1/2} \qquad \text{(Equation 1)}$$

where δ = solubility parameter $((cal/cm^3)^{1/2})$
ΔE = energy of vaporization (cal)
V = molar volume (cm^3)

("Polymer Handbook", 2nd Ed., Brandrup J. and EH Immergut, ed., Wiley-Interscience, John Wiley & Sons, N.Y. (1975)). Because polymers are typically non-volatile and thus cannot be vaporized without decomposition, the solubility parameter is measured indirectly. Briefly, solvents in which a polymer dissolves without a change in heat or volume are identified. The solubility parameter of the polymer is then defined to be the same as the solubility parameters of the identified solvents.

[0020] As a general rule, the value of the solubility parameter δ is inversely proportional to the degree of hydrophobicity of a polymer. Polymers that are very hydrophobic may have a low solubility parameter value. This general proposition is particularly applicable for polymers having a glass transition temperature below physiological temperature. A polymer that is sufficiently hydrophobic for use in the rate-limiting membrane of the present invention can have a solubility parameter of not more than about 10.7 $(cal/cm^3)^{1/2}$. Representative examples of such crystalline, hydrophobic polymers include polytetrafluoroethylene, ethylene-tetrafluoroethylene copolymer, fluoroethylene-alkyl vinyl ether copolymer, polyhexafluoropropene, low density linear polyethylenes having high molecular weights, ethylene-olefin copolymers, styrene-ethylene-styrene block copolymers, styrene-butylene-styrene block copolymers, styrene-ethylene/butylene-styrene block copolymers, styrene-butadiene-styrene block copolymers, styrenic block copolymers including KRATON™ polymers (available from KRATON™ Polymers, Houston, Texas), ethylene-anhydride copolymers, ethylene-acrylic acid copolymers, poly (vinylidene fluoride), ethylene methacrylic acid copolymers,

polyurethanes with a polydimethylsiloxane soft segment, poly(vinylidene fluoride-co-hexafluoropropene), and polycarbonate urethanes (e.g., BIONATE 55D and BIONATE 75D).

[0021] Polymers of relatively high crystallinity can also maintain their crystallinity in an aqueous environment. Highly crystalline polymers are typically rigid, have high melting temperatures, and are minimally affected by solvent penetration. Since the degree and strength of crystallinity of a polymer can be roughly approximated by the melting temperature of the polymer, sufficiently high crystallinity for use with the present invention is possessed by polymers having a melting temperature greater than or equal to about 135°C at ambient pressure. Representative examples of polymers having a melting temperature of at least 135°C at ambient pressure include, but are not limited to, nylon 6, poly (vinylidene fluoride), poly (vinylidene fluoride-co-hexafluoropropene), polytetrafluoroethylene, polyetheretherketone (PEEK), polyimide, polysulfone, ethylene-co-methacrylic acid, ethylene-co-acrylic acid, and styrenic block copolymers including KRATON™ polymers (available from KRATON™ Polymers, Houston, Texas).

[0022] The above-described suitably crystalline polymers can be used to form a rate-reducing coating onto a medical device. The embodiments of the composition for such a coating can be prepared by conventional methods wherein a predetermined amount of a suitable polymeric compound is added to a predetermined amount of a compatible solvent. "Solvent" is defined as a liquid substance or composition that is mutually compatible with a polymer and is

capable of significantly dissolving the polymer at the concentration desired in the composition. Examples of solvents include, but are not limited to, dimethylsulfoxide (DMSO), chloroform, acetone, xylene, methanol, ethanol, 1-propanol, tetrahydrofuran, 1-butanone, dimethylformamide, dimethylacetamide, cyclohexanone, ethyl acetate, methylethylketone, propylene glycol monomethylether, isopropanol, isopropanol admixed with water, N-methyl pyrrolidinone, toluene, hexafluoroisopropanol, methylene chloride, hexamethylphosphorous triamide, N-methylmorpholine, trifluoroethanol, formic acid, and phenol. The polymeric compound can be added to the solvent at ambient pressure and under anhydrous atmosphere. The polymeric compound is soluble before crystallization in a solvent system at, for example, temperatures of less than or equal to about 80°C. If necessary, gentle heating and stirring and/or mixing can be employed to effect dissolution of the polymer into the solvent, for example 12 hours in a water bath at about 60°C.

[0023] Application of the composition can be by any conventional method, such as by spraying the composition onto the device or by immersing the device in the composition. Operations such as wiping, centrifugation, blowing, or other web-clearing acts can also be performed to achieve a more uniform coating. Briefly, wiping refers to physical removal of excess composition from the surface of the stent; centrifugation refers to rapid rotation of the stent about an axis of rotation; and blowing refers to application of air at a selected pressure to the deposited composition. Any excess composition can also be vacuumed off of the surface of the device. The solvent is removed from the composition to form the rate-reducing

coating by allowing the solvent to evaporate. The evaporation can be induced by heating the device at a predetermined temperature for a predetermined period of time. For example, the device can be heated at a temperature of about 60° C for about 1 hour to about 12 hours. The heating can be conducted in an anhydrous atmosphere and at ambient pressure and should not exceed the temperature that would adversely affect the active agent. The heating can, alternatively, be conducted under a vacuum condition. It is understood that essentially all of the solvent will be removed from the composition, but traces or residues may remain blended with the polymer.

Examples of the Device

[0024] A medical device for use in conjunction with the above-described rate-reducing coating is broadly defined to include any inter- or intraluminal device used for the release of an active agent and/or for upholding the luminal patency in a human or veterinary patient. Examples of such implantable devices include self-expandable stents, balloon-expandable stents, stent-grafts, grafts (e.g., aortic grafts), artificial heart valves, cerebrospinal fluid shunts, pacemaker electrodes, anastomosis devices such as axius coronary shunts and endocardial leads (e.g., FINELINE and ENDOTAK, available from Guidant Corporation). The underlying structure of the device can be of virtually any design. The device can be made of a metallic material or an alloy such as, but not limited to, cobalt chromium alloy (ELGILOY), stainless steel (316L), "MP35N," "MP20N," ELASTINITE (Nitinol), tantalum, nickel-titanium alloy, platinum-iridium alloy, gold, magnesium, or combinations thereof. "MP35N" and "MP20N" are trade names for alloys of

cobalt, nickel, chromium and molybdenum available from standard Press Steel Co., Jenkintown, PA. "MP35N" consists of 35% cobalt, 35% nickel, 20% chromium, and 10% molybdenum. "MP20N" consists of 50% cobalt, 20% nickel, 20% chromium, and 10% molybdenum. Devices made from bioabsorbable or biostable polymers could also be used with the embodiments of the present invention.

Use of the Rate-Reducing Coating

[0025] In one embodiment, the above-described rate-reducing coating, free from therapeutic substances or active agents, can function as a barrier layer through which an underlying therapeutic substance or active agent must diffuse to be released from a device into a treatment site. The active agent can be carried by the device, such as in porous cavities in the surface of the device, or can be impregnated in a reservoir polymer layer formed beneath the rate-reducing coating. Such a rate-reducing barrier coating can be of any suitable thickness. The thickness of the coating can be from about 0.01 microns to about 20 microns, more narrowly from about 0.1 microns to about 10 microns. By way of example, the rate-reducing barrier coating can have a thickness of about 3 microns.

[0026] In another embodiment, the rate-reducing coating can additionally function as a reservoir for carrying the therapeutic substance or active agent. In such an embodiment, sufficient amounts of an active agent can be dispersed in the blended composition of the suitably crystalline polymer and the solvent. The polymer can comprise from about 0.1% to about 35%, more narrowly from about 2% to about 20% by weight of the total weight of the composition, the solvent can

comprise from about 59.9% to about 99.8%, more narrowly from about 79% to about 89% by weight of the total weight of the composition, and the active agent can comprise from about 0.1% to about 40%, more narrowly from about 1% to about 9% by weight of the total weight of the composition.

[0027] The active agent should be in true solution or saturated in the blended composition. If the active agent is not completely soluble in the composition, operations including mixing, stirring, and/or agitation can be employed to effect homogeneity of the residues. The active agent may be added so that the dispersion is in fine particles.

[0028] The active agent can be for inhibiting the activity of vascular smooth muscle cells. More specifically, the active agent can be aimed at inhibiting abnormal or inappropriate migration and/or proliferation of smooth muscle cells for the inhibition of restenosis. The active agent can also include any substance capable of exerting a therapeutic or prophylactic effect in the practice of the present invention. For example, the agent can be for enhancing wound healing in a vascular site or improving the structural and elastic properties of the vascular site. Examples of agents include antiproliferative substances such as actinomycin D, or derivatives and analogs thereof (manufactured by Sigma-Aldrich 1001 West Saint Paul Avenue, Milwaukee, WI 53233; or COSMEGEN available from Merck). Synonyms of actinomycin D include dactinomycin, actinomycin IV, actinomycin I_1, actinomycin X_1, and actinomycin C_1. The active agent can also fall under the genus of antineoplastic, antiinflammatory, antiplatelet, anticoagulant, antifibrin, antithrombin, antimitotic, antibiotic, antiallergic and antioxidant substances.

Examples of such antineoplastics and/or antimitotics include paclitaxel (e.g. TAXOL® by Bristol-Myers Squibb Co., Stamford, Conn.), docetaxel (e.g. Taxotere®, from Aventis S.A., Frankfurt, Germany) methotrexate, azathioprine, vincristine, vinblastine, fluorouracil, doxorubicin hydrochloride (e.g. Adriamycin® from Pharmacia & Upjohn, Peapack N.J.), and mitomycin (e.g. Mutamycin® from Bristol-Myers Squibb Co., Stamford, Conn.). Examples of such antiplatelets, anticoagulants, antifibrin, and antithrombins include sodium heparin, low molecular weight heparins, heparinoids, hirudin, argatroban, forskolin, vapiprost, prostacyclin and prostacyclin analogues, dextran, D-phe-pro-arg-chloromethylketone (synthetic antithrombin), dipyridamole, glycoprotein IIb/IIIa platelet membrane receptor antagonist antibody, recombinant hirudin, and thrombin inhibitors such as Angiomax ™ (Biogen, Inc., Cambridge, Mass.). Examples of such cytostatic or antiproliferative agents include angiopeptin, angiotensin converting enzyme inhibitors such as captopril (e.g. Capoten® and Capozide® from Bristol-Myers Squibb Co., Stamford, Conn.), cilazapril or lisinopril (e.g. Prinivil® and Prinzide® from Merck & Co., Inc., Whitehouse Station, NJ); calcium channel blockers (such as nifedipine), colchicine, fibroblast growth factor (FGF) antagonists, fish oil (omega 3-fatty acid), histamine antagonists, lovastatin (an inhibitor of HMG-CoA reductase, a cholesterol lowering drug, brand name Mevacor® from Merck & Co., Inc., Whitehouse Station, NJ), monoclonal antibodies (such as those specific for Platelet-Derived Growth Factor (PDGF) receptors), nitroprusside, phosphodiesterase inhibitors, prostaglandin inhibitors, suramin, serotonin blockers, steroids, thioprotease inhibitors, triazolopyrimidine (a PDGF antagonist), and nitric oxide. An example of an

antiallergic agent is permirolast potassium. Other therapeutic substances or agents which may be appropriate include alpha-interferon, genetically engineered epithelial cells, rapamycin and dexamethasone. Exposure of the active agent to the composition should not adversely alter the active agent's composition or characteristic. Accordingly, the particular active agent is selected for compatibility with the solvent or blended polymer-solvent.

[0029] In one embodiment, an optional primer layer can be formed on the outer surface of the medical device. Formation of a primer layer, free from any active agents, can be by any conventional method, such as by spraying a primer composition containing a polymer and a compatible solvent onto the medical device or immersing the medical device in the primer composition followed by evaporation of the solvent. The polymer selected can be any polymer suitable for coating a medical device. With the use of thermoplastic polymers such as, but not limited to, ethylene vinyl alcohol copolymer, polycaprolactone, poly(lactide-co-glycolide), and poly(hydroxybutyrate), the deposited primer composition should be exposed to a heat treatment at a temperature range greater than about the glass transition temperature (T_g) and less than about the melting temperature (T_m) of the selected polymer. Unexpected results have been discovered with treatment of the composition under this temperature range, specifically strong adhesion or bonding of the coating to the metallic surface of a stent. The medical device should be exposed to the heat treatment for any suitable duration of time that will allow for the formation of the primer layer on the outer surface of the device and for the evaporation of the solvent employed. It is understood that essentially all of the

solvent will be removed from the primer composition but traces or residues can remain blended with the polymer.

[0030] In other embodiments, the crystalline coating can be topcoated with one or more additional coating layers. Such additional coating layers can be for increasing the biocompatibility of the device. For example, in one embodiment, the additional coating layer can be formed from ethylene vinyl alcohol (EVAL), polyethylene glycol, polyethylene oxide, hyaluronic acid, heparin, or heparin derivatives having hydrophobic counterions, thereby providing biocompatibility to the outermost, tissue-contacting surface of the medical device.

[0031] In another embodiment, an additional coating layer can serve as yet another rate-reducing layer. Because the additional rate-reducing layer does not contain active agents, the methods by which such a layer is deposited is not limited to the methods by which the polymer layers having active agents are applied. Therefore, in addition to application by conventional methods, such as by spraying a polymeric composition onto the device or by immersing the device in a polymeric composition, the additional rate-reducing layers can be deposited by physical vapor deposition (PVD) techniques, which are known to one of ordinary skill in the art. Representative examples of barrier materials that can be deposited via PVD techniques include plasma-deposited polymers, parylene C, parylene N, parylene D, perfluoro parylene, tetrafluoro (AF4) parylene, metallic layers, metallic oxides, metal carbides, and metal nitrides.

Methods of Use

[0032] In accordance with embodiments of the above-described method, an active agent can be applied to an implantable medical device or prosthesis, e.g., a stent, retained on the stent during delivery and expansion of the stent, and released at a desired control rate and for a predetermined duration of time at the site of implantation. A stent having the above-described coating is useful for a variety of medical procedures, including, by way of example, treatment of obstructions caused by tumors in bile ducts, esophagus, trachea/bronchi and other biological passageways. A stent having the above-described coating is particularly useful for treating occluded regions of blood vessels caused by abnormal or inappropriate migration and proliferation of smooth muscle cells, thrombosis, and restenosis. Stents may be placed in a wide array of blood vessels, both arteries and veins. Representative examples of sites include the iliac, renal, and coronary arteries.

[0033] Briefly, an angiogram is first performed to determine the appropriate positioning for stent therapy. An angiogram is typically accomplished by injecting a radiopaque contrasting agent through a catheter inserted into an artery or vein as an x-ray is taken. A guidewire is then advanced through the lesion or proposed site of treatment. Over the guidewire is passed a delivery catheter that allows a stent in its collapsed configuration to be inserted into the passageway. The delivery catheter is inserted either percutaneously or by surgery into the femoral artery, brachial artery, femoral vein, or brachial vein, and advanced into the appropriate blood vessel by steering the catheter through the vascular system under fluoroscopic guidance. A stent having the above-described coating may then be

expanded at the desired area of treatment. A post-insertion angiogram may also be utilized to confirm appropriate positioning.

EXAMPLES

[0034] The embodiments of the invention will be illustrated by the following set forth prophetic examples, which are being given by way of illustration only and not by way of limitation. All parameters are not to be construed to unduly limit the scope of the embodiments of the invention.

Example 1

[0035] A 2% (w/w) solution of EVAL in dimethylacetamide (DMAC) is applied to a 13 mm Tetra™ stent (available from Guidant Corporation) using an EFD 780S spray device (available from EFD Inc., East Providence, RI) until 50 micrograms of solids have been deposited onto the stent. The stent is baked at 140°C for 60 minutes to form a primer layer on the stent. A solution of 1:9 (w/w) actinomycin D:EVAL and 2% (w/w) EVAL in DMAC is sprayed onto the primered stent until 100 micrograms of solids have been deposited. The stent is baked at 50°C for 2 hours to form an actinomycin D-containing reservoir coating. A 2% (w/w) polyvinylidene fluoride solution in DMAC is sprayed until 300 micrograms of solids have been deposited onto the stent. The stent is baked at 50°C for 2 hours to form a crystalline rate-reducing membrane of polyvinylidene fluoride.

Example 2

[0036] A 2% (w/w) solution of EVAL in DMAC is applied to a 13 mm Tetra™ stent using an EFD 780S spray device until 50 micrograms of solids have been deposited onto the stent. The stent is baked at 140°C for 60 minutes to form a primer layer on the stent. A solution of 1:3 (w/w) dexamethasone:poly(ethylene-co-vinyl-acetate) and 2% (w/w) poly(ethylene-co-vinyl-acetate) in cyclohexanone is sprayed onto the primered stent until 300 micrograms of solids have been deposited. The stent is baked at 60°C for 2 hours to form a dexamethasone-containing reservoir coating. A 2% (w/w) KRATON G1650 (available from KRATON™ Polymers, Houston, Texas) solution in xylene is sprayed until 300 micrograms of solids have been deposited onto the stent. The stent is baked at 60°C for 2 hours to form a crystalline rate-reducing membrane of KRATON G1650.

Example 3

[0037] A 2% (w/w) solution of EVAL in DMAC is applied to a 13 mm Tetra™ stent using an EFD 780S spray device until 50 micrograms of solids have been deposited onto the stent. The stent is baked at 140°C for 60 minutes to form a primer layer on the stent. A solution of 1:2 (w/w) estradiol:EVAL and 2% (w/w) EVAL in DMAC is sprayed onto the primered stent until 350 micrograms of solids have been deposited. The stent is baked at 60°C for 2 hours to form an estradiol-containing reservoir coating. A 2% (w/w) poly(vinylidene fluoride-co-hexafluoropropene) solution in 1:1 (w/w) acetone:DMAC is sprayed until 300 micrograms of solids have been deposited onto the stent. The stent is baked at 60°C for 2 hours to form a crystalline rate-reducing membrane of poly(vinylidene fluoride-co-hexafluoropropene).

Example 4

[0038] A 2% (w/w) solution of poly(n-butyl methacrylate) in 4:1 (w/w) acetone:cyclohexanone is applied to a 13 mm Tetra™ stent using an EFD 780S spray device until 50 micrograms of solids have been deposited onto the stent. The stent is baked at 70°C for 60 minutes to form a primer layer on the stent. A solution of 1:2 (w/w) etoposide:EVAL and 2% (w/w) EVAL in DMAC is sprayed onto the primered stent until 300 micrograms of solids have been deposited. The stent is baked at 60°C for 2 hours to form an etoposide-containing reservoir coating. A 1.5% (w/w) silicone-urethane Elast-Eon™ 55D (available from Elastomedic Pty Ltd., Australia) solution in 1:1 (w/w) THF:DMAC is sprayed until 300 micrograms of solids have been deposited onto the stent. The stent is baked at 60°C for 2 hours to form a crystalline rate-reducing membrane of silicone-urethane Elast-Eon™ 55D.

[0039] While particular embodiments of the present invention have been shown and described, it will be obvious to those skilled in the art that changes and modifications can be made without departing from this invention in its broader aspects and, therefore, the appended claims are to encompass within their scope all such changes and modifications as fall within the true spirit and scope of this invention.

CLAIMS

What is claimed is:

1. A stent for delivery of a therapeutic agent, comprising:

a polymer coating for reducing the rate of release of the therapeutic agent, the polymer having a crystalline structure, wherein the polymer is capable of significantly maintaining the crystalline structure while the therapeutic agent is released from the stent such that the aqueous environment to which the stent is exposed subsequent to the implantation of the stent does not significantly convert the crystalline structure of the polymer to an amorphous structure.

2. The stent of Claim 1, wherein the crystallinity of the polymer is not less than about 50% prior to the implantation of the stent or not less than about 25% when exposed to the aqueous environment subsequent to the implantation of the stent.

3. The stent of Claim 1, wherein the melting point of the polymer is greater than or equal to about 135°C at ambient pressure.

4. The stent of Claim 1, wherein the polymer is a hydrophobic polymer having a solubility parameter of not more than about 10.7 $(cal/cm^3)^{1/2}$.

5. The stent of Claim 1, wherein the polymer is selected from a group of polytetrafluoroethylene, ethylene-tetrafluoroethylene copolymer, fluoroethylene-alkyl vinyl ether copolymer, polyhexafluoropropene, low density linear

polyethylenes having high molecular weights, ethylene-olefin copolymers, styrene-ethylene-styrene block copolymers, styrene-butylene-styrene block copolymers, styrene-ethylene/butylene-styrene block copolymers, styrene-butadiene-styrene block copolymers, ethylene-anhydride copolymers, ethylene-acrylic acid copolymers, styrenic block copolymers, ethylene methacrylic acid copolymers, polyurethanes with a polydimethylsiloxane soft segment, poly(vinylidene fluoride-co-hexafluoropropene), poly(vinylidene fluoride), and polycarbonate urethanes.

6. The stent of Claim 1, wherein the polymer is selected from a group of nylon 6, polytetrafluoroethylene, polyetheretherketone, polyimide, polysulfone, ethylene-co-methacrylic acid, ethylene-co-acrylic acid, poly(vinylidene fluoride), poly(vinylidene fluoride-co-hexafluoropropene) and styrenic block copolymers.

7. The stent of Claim 1, wherein the coating contains the therapeutic agent for delivery of the therapeutic agent.

8. The stent of Claim 7, additionally comprising:

a primer layer formed on the surface of the medical device, wherein the coating is formed over the primer layer, and wherein the primer layer acts as an adhesive tie between the coating and the surface of the medical device.

9. The stent of Claim 1, additionally comprising:

a reservoir layer containing the therapeutic agent formed on the medical device, wherein the coating is formed over at least a region of the reservoir layer to reduce the rate of release of the therapeutic agent.

10. The stent of Claim 1, additionally comprising:

a primer layer formed on the surface of the medical device; and

a reservoir layer containing the therapeutic agent formed on the primer layer, wherein the coating is formed on at least a portion of the reservoir layer to reduce the rate of release of the therapeutic agent.

11. A method of forming a coating for a stent for reducing the rate of release of a therapeutic agent from the stent, comprising:

applying a first composition including a polymeric material to at least a portion of the stent to form a polymer coating supported by the stent, the polymer having a crystalline structure, wherein the aqueous environment to which the coating is exposed subsequent to the implantation of the stent does not significantly convert the crystalline structure of the polymer to an amorphous structure for the duration of time which the agent is released from the stent.

12. A stent comprising a polymeric coating, the coating being produced in accordance with the method of Claim 11.

13. The method of Claim 11, wherein the crystallinity of the polymeric material is not less than about 25% during the release of the therapeutic agent from the stent.

14. The method of Claim 11, wherein the polymeric material has a solubility parameter not more than about 10.7 $(cal/cm^3)^{1/2}$.

15. The method of Claim 11, wherein the polymeric material has a melting point greater than or equal to about 135°C at ambient pressure.

16. The method of Claim 11, wherein the polymer is selected from a group of polytetrafluoroethylene, ethylene-tetrafluoroethylene copolymer, fluoroethylene-alkyl vinyl ether copolymer, polyhexafluoropropene, poly(vinylidene fluoride), low density linear polyethylenes having high molecular weights, ethylene-olefin copolymers, styrene-ethylene-styrene block copolymers, styrene-butylene-styrene block copolymers, styrene-ethylene/butylene-styrene block copolymers, styrene-butadiene-styrene block copolymers, styrenic block copolymers, ethylene-anhydride copolymers, ethylene-acrylic acid copolymers, ethylene methacrylic acid copolymers, polyurethanes with a polydimethylsiloxane soft segment, poly(vinylidene fluoride-co-hexafluoropropene), and polycarbonate urethanes.

17. The method of Claim 11, wherein the polymer is selected from a group of nylon 6, polytetrafluoroethylene, polyetheretherketone, polyimide, polysulfone, ethylene-co-methacrylic acid, ethylene-co-acrylic acid,

poly(vinylidene fluoride), poly(vinylidene fluoride-co-hexafluoropropene), and styrenic block copolymers.

18. A composition for coating a stent, comprising:

a) a fluid; and

b) a polymer dissolved in the fluid, wherein the polymer comprises a crystalline structure during the duration of delivery of an active agent from the stent and wherein the aqueous environment to which the stent is exposed subsequent to the implantation procedure does not significantly change the crystalline structure to an amorphous structure.

19. A stent for delivering a therapeutic agent to an implanted site, comprising:

a radially expandable body structure; and

a polymeric coating supported by the body structure for extending the residence time of the therapeutic agent at the implanted site, wherein the polymeric coating is made from a hydrophobic polymer having a degree of crystallinity that remains at or above about 10% at least until a significant amount of the therapeutic substance has been released from the stent.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 02/27521

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61L31/10 A61L31/16

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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X	WO 01 45763 A (ADVANCED CARDIOVASCULAR SYSTEM) 28 June 2001 (2001-06-28) claims; examples	1-19
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[X] Further documents are listed in the continuation of box C.

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15 November 2002	25/11/2002

Name and mailing address of the ISA	Authorized officer
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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(54) Title: POLYESTERAMIDE, ITS PREPARATION AND SURGICAL DEVICES FABRICATED THEREFROM

(57) Abstract

Degradable polyesteramide suitable for use in biomedical applications is obtained by reacting diamino alkyl ester with alpha hydroxy acid to form diamide–diol which is reacted with acyl halide or dicarboxylic acid to yield polyesteramide.

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POLYESTERAMIDE, ITS PREPARATION AND SURGICAL DEVICES FABRICATED THEREFROM

TECHNICAL FIELD

An absorbable polyesteramide, its preparation and absorbable surgical devices fabricated therefrom such as monofilament and multifilament sutures, films, sheets, plates, clips, staples, pins, screws, and the like are described herein.

BACKGROUND

Polyesteramides are polymers containing both ester linkages and amide linkages. Their significance for technology of surgical devices stems from the fact that the susceptibility of their ester linkages to hydrolysis confers upon them the ability to be eventually absorbed, or resorbed by a body into which they have been implanted and their amide linkages confer upon them the desirable mechanical properties characteristic of polyamides.

Fiber-forming polyesteramides obtained from the single stage reaction of approximately equimolar amounts of a monoalkanolamine and a dicarboxylic acid are known from U.S. Patent No. 2,386,454. Polyesteramides indicated to be useful for the manufacture of absorbable sutures and other surgical devices are disclosed in U.S. Patent No. 4,226,243 as obtained from the reaction of a bis-oxyamidodiol (itself derived from the reaction of diethyl oxalate with a monoalkanolamine such as ethanolamine) with a dicarboxylic acid ester. U.S. Patent No 4,343,931 discloses absorbable surgical devices manufactured from polyesteramides obtained by reacting a diamide with lactic or glycolic acid to produce a diamidediol, which is then reacted with a bischloroformate or a compound selected from the group

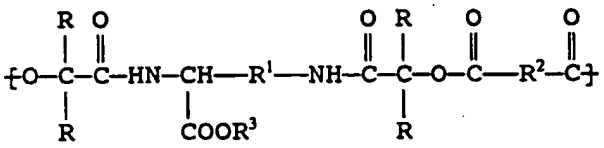
consisting of dicarboxylic acids, diacidchlorides and dicarboxylic acid anhydrides.

Nylon refers to a family of high strength, resilient synthetic materials, the long chain molecules of which contain recurring amide groups. Articles made from Nylon have been widely accepted for a variety of applications. Certain surgical applications, however, require a surgical device that is bioabsorbable. Nylon is not bioabsorbable and is therefore unacceptable in such circumstances.

It would be desirable to provide a surgical device material that has strength and resiliency characteristics equivalent to those of nylon, but which is bioabsorbable.

SUMMARY

A biodegradable polyesteramide is provided having units of the following formula:



in which R is hydrogen, methyl or ethyl;

R^1 and R^2 may be identical or different and are selected from the group consisting of linear alkyl, branched alkyl, linear alkylene, branched alkylene, oxa-alkylene, cycloalkylene and arylene; and

R^3 may be hydrogen, linear or branched alkyl, or linear or branched alkylene.

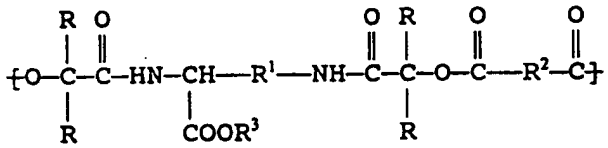
A method of making biodegradable polyesteramide is provided which includes reacting an amino alkyl ester with alpha hydroxy acid to form diamide-diol and reacting diamide-diol with acyl halide to form the polyesteramide.

A surgical implant including a biocompatible polyesteramide is also provided.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The polyesteramide herein is biodegradable and in certain aspects biocompatible and suitable for use in medicine. Such polyesteramides combine the good mechanical properties of polyamides with the degradability of polyesters.

Polyesteramides in accordance with the present disclosure have the following formula:



in which R is hydrogen, methyl or ethyl;

R^1 and R^2 may be identical or different and are selected from the group consisting of linear alkyl, branched alkyl, linear alkylene, branched alkylene, oxa-alkylene, cycloalkylene and arylene; and

R^3 may be hydrogen, linear or branched alkyl, or linear or branched alkylene.

To obtain such polyesteramide, diamino alkyl ester is reacted with alpha hydroxy acid in the presence of suitable solvent and suitable acid such as aromatic sulfonic acid, an aliphatic acid and inorganic acid, at elevated temperatures to yield diamide-diol. The diamide-diol is converted into a bioabsorbable polymer by reaction with a diacyl halide or dicarboxylic acid.

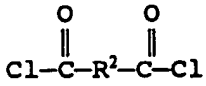
Suitable amino acid esters include lysine alkyl esters such as lysine methyl ester and lysine ethyl ester. Suitable hydroxyacids include glycolic acid and lactic acid. Suitable solvents include toluene, acetonitrile, methylene

chloride and chloroform. Aromatic sulfonic acids which may be used include p-toluene sulfonic acid. Aliphatic acids which may be used include aceteic acid. Inorganic acids which may be used include hydrochloric acid and sulfuric acid.

A preferred method involves reacting about 1 mole of amino alkyl ester with about 2 moles of alpha hydroxy acid at a temperature of between about 100°C and about 150°C in toluene and about 1% to 5% by weight p-toluene sulfonic acid as a catalyst. Distillation may be used to remove excess water by-product.

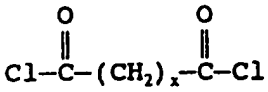
The resulting diamide-diol is dissolved in a solvent which is non-reactive with diacyl halides or dicarboxylic acid and which has a boiling point of about 100°C or higher. Suitable solvents include tolulene, xylene or chlorobenzene. The diamide-diol can be refluxed at elevated temperatures with equimolar amounts of diacyl halide or dicarboxylic acid. Reflux temperatures may range from about 100°C to about 150°C. Chlorobenzene is a preferred solvent.

Preferred diacyl halides are diacyl chlorides of the following formula



wherein R2 is selected from the group consisting of linear alkyl, branched alkyl, linear alkylene, branched alkylene, oxa-alkylene, cycloalkylene and arylene.

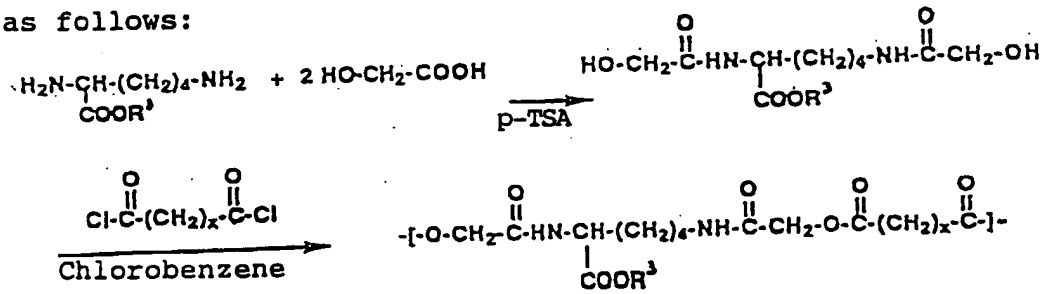
In a preferred aspect, diacyl chloride of the following formula is utilized:



wherein X is a number ranging from 0 to 10.

Also suitable for use in place of diacyl halide are diacid dimethyl or diethyl esters of dicarboxylic acid. Dicarboxylic acids herein include methyl and ethyl esters thereof and acid chlorides and anhydrides thereof. Examples include, but are not limited to oxalic acid; malonic acid; succinic acid; 2,3-dimethylsuccinic acid; glutaric acid; 3,3-dimethylglutaric acid; 3-methyladipic acid; adipic acid; pimelic acid; suberic acid; azelaic acid; sebacic acid; 1,9-nonanedicarboxylic acid; 1,10-decanedicarboxylic acid; 1,11-undecanedicarboxylic acid; 1,12-dodecanedicarboxylic acid, 1,13-tridecanedicarboxylic acid; 1,14-tetradecane-dicarboxylic acid; 1,15-pentadecanedicarboxylic acid; 1,16-hexadecanedicarboxylic acid; maleic acid; trans-β-hydromuconic acid; fumaric acid; diglycolic acid; 3,3'-oxydipropionic acid; 4,4'-oxydibutyric acid; 4,5'-oxydivaleric acid; 6,6'-oxydicaproic acid; 8,8'-oxydicaprylic acid; 6-oxaundecanedioic acid; 5-oxaazelaic acid; 5-oxadodecanedioic acid; 5-oxatetradecanedioic acid; 5-oxahexadecanedioic acid; 6-oxadodecanedioic acid; 6-oxatridecanedioic acid; 6-oxapentadecanedioic acid; 6-oxaheptadecanedioic acid; 7-oxapentadecanedioic acid; 10-oxanonadecanedioic acid and other oxa-aliphatic dicarboxylic acids; phthalic acid; isophthalic acid; tetrephthalic acid and other aromatic dicarboxylic acids; 1,2-cyclobutanedicarboxylic acid; and 1,4-cyclohexane-dicarboxylic acid.

In a preferred aspect, the reaction may be illustrated as follows:



wherein R^3 is CH_3 or CH_2CH_3 and X is a number ranging from 0 to 10.

The degradable polyesteramide herein is suitable for use in a wide variety of applications. Since the degradation products of the biocompatable polymer herein are non-toxic, it is suitable for biomedical uses. For example, depending on the number of ester linkages in the polymeric chain, the polymer can be made to degrade slowly and can thus be utilized for fabricating long term implantable surgical materials. Examples of implants include prosthetic devices, sutures, staples, clips and other fasteners, screws, pins, films, meshes, drug delivery devices, anastomosis rings, surgical dressings and the like. The polyesteramides herein may also be used to fabricate degradable containers and packaging materials which can degrade in landfills in contrast to nondegradable materials which present environmental concerns.

Optional additives which may be present in compositions made from the polyesteramides described herein include plasticizers, release agents and other processing acids. Where the composition is used to make a surgical device, stearic acid or calcium stearate are particularly useful additives due to their biocompatibility.

The polyesteramides can be formed into surgical articles using any known technique, such as, for example, extrusion, molding and/or solvent casting. The polyesteramides can be used alone; blended with other absorbable compositions, or in combination with non-absorbable components. As mentioned above, a wide variety of surgical articles can be manufactured from the polyesteramides described herein. Fibers made from the present polyesteramides can be knitted or woven with other fibers, either absorbable or nonabsorbable to form meshes or fabrics. Compositions including these polyesteramides can

also be used as an absorbable coating for surgical devices.

In an alternative embodiment, the polyesteramides described herein are admixed with a filler. The filler can be in any particulate form, including granulate and staple fibers. While any known filler may be used, hydroxyapatite, tricalcium phosphate, bioglass or other bioceramics are the preferred fillers. Normally, from about 10 grams to about 400 grams of filler are mixed with 100 grams of polymer. The filled, cross-linked polymers are useful, for example, as a molding composition.

In another aspect, compositions containing the polyester amides described herein can be used to make reinforced composites. Thus, for example, the polyesteramide composition can form the matrix of the composite and can be reinforced with bioabsorbable or non-absorbable fibers or particles. Alternatively, a matrix of any bioabsorbable or non-bioabsorbable polymer composition can be reinforced with fibers or particulate material made from compositions containing the polyesteramides described herein.

It is further contemplated that one or more medico-surgically useful substances can be incorporated into compositions containing the polyesteramides described herein. Examples of such medico-surgically useful substances include, for example, those which accelerate or beneficially modify the healing process when particles are applied to a surgical repair site. So, for example, articles made from compositions containing the present polyesteramides can carry a therapeutic agent which will be deposited at the repair site. The therapeutic agent can be chosen for its antimicrobial properties, capability for promoting repair or reconstruction and/or new tissue growth. Antimicrobial agents such as broad spectrum antibiotic (gentamycin sulfate, erythromycin or derivatized

glycopeptides) which are slowly released into the tissue can be applied in this manner to aid in combating clinical and sub-clinical infections in a tissue repair site. To promote repair and/or tissue growth, one or several growth promoting factors can be introduced into the articles, e.g., fibroblast growth factor, bone growth factor, epidermal growth factor, platelet derived growth factor, macrophage derived growth factor, alveolar derived growth factor, monocyte derived growth factor, magainin, and so forth. Some therapeutic indications are: glycerol with tissue or kidney plasminogen activator to cause thrombosis, superoxide dimutase to scavenge tissue damaging free radicals, tumor necrosis factor for cancer therapy or colony stimulating factor and interferon, interleukin-2 or other lymphokine to enhance the immune system. It is also contemplated that medico-surgically useful substances can include non-therapeutic agents such as dyes, which typically do not exert biological activity per se.

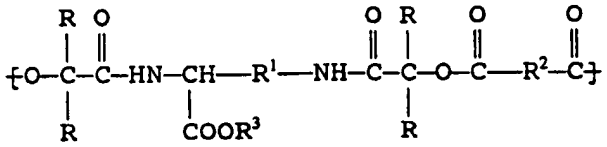
It is contemplated that it may be desirable to dye articles made from compositions containing the present polyesteramides in order to increase visibility of the article in the surgical field. Dyes, such as those known to be suitable for incorporation in sutures, can be used. Such dyes include but are not limited to carbon black, bone black, D&C Green No. 6, and D&C Violet No. 2 as described in the handbook of U.S. Colorants for Food, Drugs and Cosmetics by Daniel M. Marrion (1979). Preferably, sutures in accordance with this disclosure are dyed by adding up to about a few percent and preferably about 0.2% dye to the resin composition prior to extrusion.

It will be understood that various modifications may be made to the embodiments disclosed herein. Therefore the above description should not be construed as limiting, but merely as exemplifications of preferred embodiments. Those

skilled in the art will envision other modifications within the scope and spirit of the claims appended hereto.

WHAT IS CLAIMED IS:

1. A polymer comprising polyesteramide units of the following formula:

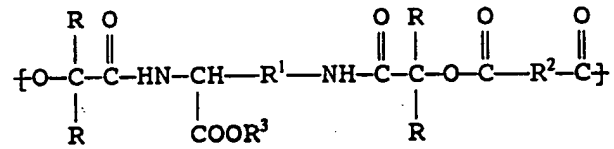


wherein R is selected from the group consisting of hydrogen, methyl and ethyl;

R^1 and R^2 may be identical or different, and are selected from the group consisting of linear alkyl, branched alkyl, linear alkylene, branched alkylene, oxa-alkylene, cycloalkylene and arylene; and

R^3 is selected from the group consisting of hydrogen, linear alkyl, branched alkyl, linear alkylene, and branched alkylene.

2. A surgical implant comprising a biocompatible polyesteramide including units of the following formula:



wherein R is selected from the group consisting of hydrogen, methyl and ethyl;

R^1 and R^2 may be identical or different, and are selected from the group consisting of linear alkyl, branched alkyl, linear alkylene, branched alkylene, oxa-alkylene, cycloalkylene and arylene; and

R^3 is selected from the group consisting of hydrogen, linear alkyl, branched alkyl, linear alkylene and branched alkylene.

3. A surgical implant according to claim 2 wherein the implant is bioabsorbable.

4. A surgical implant according to claim 2 wherein the implant is selected from the group consisting of suture, staple, clip, screws, pin, film, sheet, mesh, drug delivery device and prosthetic device.

5. A method of making a degradable polyesteramide comprising:

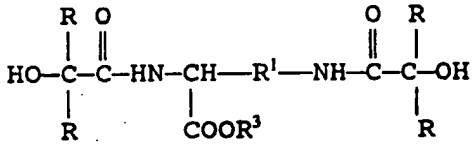
reacting amino alkyl ester with alphahydroxy acid to form diamide-diol; and

reacting diamide-diol with diacyl-halide or dicarboxylic acid to form polyesteramide.

6. A method of making a biodegradable polyesteramide according to claim 5 wherein amino alkyl ester is lysine alkyl ester.

7. A method of making a biodegradable polyesteramide according to claim 5 wherein the alphahydroxy acid is selected from the group consisting of glycolic acid and lactic acid.

8. A method of making a biodegradable polyesteramide according to claim 5 wherein the diamide-diol includes the following structure:



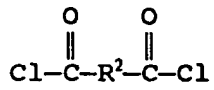
wherein R is selected from the group consisting of hydrogen, methyl and ethyl;

R^1 is selected from the group consisting of linear alkyl, branched alkyl, linear alkylene, branched alkylene, oxa-alkylene, cycloalkylene and arylene; and

R^3 is selected from the group consisting of hydrogen, linear alkyl, branched alkyl, linear alkylene and branched alkylene.

9. A method of making a biodegradable polyesteramide according to claim 5 wherein the diacyl halide is diacyl chloride.

10. A method of making a biodegradable polyesteramide according to claim 9 wherein the diacyl chloride has the following structure:



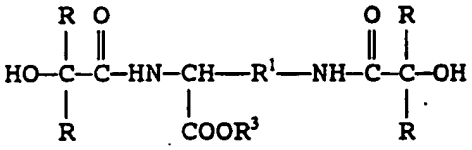
wherein R^2 is selected from the group consisting of linear alkyl, branched alkyl, linear alkylene, branched alkylene, oxa-alkylene, cycloalkylene and arylene.

11. A biodegradable polyesteramide manufactured by reacting lysine alkyl ester with alpha hydroxy acid to form diamide-diol and reacting diamide-diol with diacyl halide to form polyesteramide.

12. A biodegradable polyesteramide according to claim 11 wherein amino alkyl ester is lysine alkyl ester.

13. A biodegradable polyesteramide according to claim 11 wherein the alphahydroxy acid is selected from the group consisting of glycolic acid and lactic acid.

14. A biodegradable polyesteramide according to claim 11 wherein the diamide-diol includes the following structure:



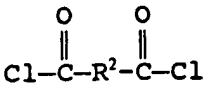
wherein R is selected from the group consisting of hydrogen, methyl and ethyl;

R^1 is selected from the group consisting of linear alkyl, branched alkyl, linear alkylene, branched alkylene, oxa-alkylene, cycloalkylene and arylene; and

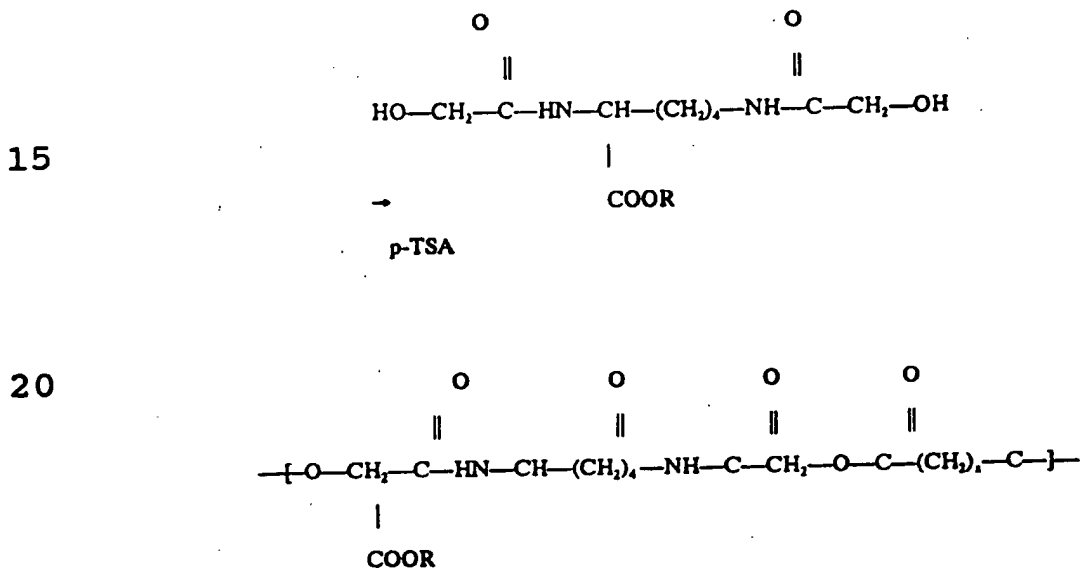
R^3 is selected from the group consisting of hydrogen, linear alkyl, branched alkyl linear alkylene and branched alkylene.

15. A biodegradable polyesteramide according to claim 11 wherein the diacyl halide is diacyl chloride.

16. A biodegradable polyesteramide according to claim 15 wherein the diacyl chloride has the following structure:



wherein R^2 is selected from the group consisting of linear alkyl, branched alkyl, linear alkylene, branched alkylene, oxa-alkylene, cycloalkylene and arylene.


HO—CH2—C—HN—CH—(CH2)4—NH—C—CH2—OH
COOR
p-TSA

—[—O—CH2—C—HN—CH—(CH2)4—NH—C—CH2—O—C—(CH2)4—C—]—
COOR

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/01676

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61F 2/00, 2/02; C08G 69/14, 69/44

US CL :523/113, 115; 528/328, 372; 525/420; 424/426; 623/11

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 523/113, 115; 528/328, 372; 525/420; 424/426; 623/11

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Please See Extra Sheet.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,505,952 A (JIANG ET AL) 09 April 1996 (09-04-96), abstract, column 2, line 50 to column 3, line 44.	5-10
Y	US 4,343,931 A (BARROWS) 10 August 1982 (10-08-82), abstract, column 1, line 57 to column 2, line 16, column 3, lines 1-40, column 4, lines 1-40.	1-16
A	US 5,324,519 A (DUNN ET AL) 28 June 1994 (28-06-94), abstract, column 2, lines 36-50, column 4, lines 64-69, column 9, lines 50-65.	1-16

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 17 APRIL 1998	Date of mailing of the international search report 05 MAY 1998
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer ANDREW E.C. MERRIAM Telephone No. (703) 308-2351

Form PCT/ISA/210 (second sheet)(July 1992)*

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/01676

B. FIELDS SEARCHED
Electronic data bases consulted (Name of data base and where practicable terms used):

APS
search terms: polyesteramide, amino acid, diamino acid, lysine, ornithine, arginine, desmosine, glycolic, lactic, lactone, lactide, glycolide, hydroxyacid, hydroxycarboxylic, acyl chloride, acyl halide, acid halide, acid chloride

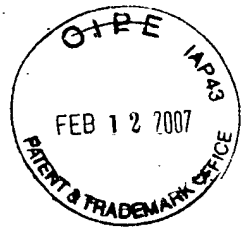
Date Mailed: February 12, 2007	By: ZL/yb	Docket No.: 50623.326
Serial No.: 10/750,139		Filed: June 3, 2004

Applicant: Jessica Reneé DesNoyer et al.

Title: Poly(ester amide) Coating Composition for Implantable Devices

The following has been received in the U.S. Patent Office on the date stamped hereon:

- ☒ Transmittal Form (1 page)
- ☒ Deposit Account Authorization 07-1850
- ☒ Response to Office Action (19 pages)
- ☒ Amendment Transmittal Letter (in duplicate) (2 pages)
- ☒ Express Mail No. EV 889 010 445 US
- ☒ Certificate of Mailing
- ☒ Statement of Common Ownership (1 page)
- ☐ Other:



#210189.1

Date Mailed: February 12, 2007	By: ZL/yb	Docket No.: 50623.326
Serial No.: 10/750,139		Filed: June 3, 2004
Applicant: Jessica Reneé DesNoyer et al.		
Title: Poly(ester amide) Coating Composition for Implantable Devices		

The following has been received in the U.S. Patent Office on the date stamped hereon:

- ☒ Transmittal Form (1 page)
- ☒ Deposit Account Authorization 07-1850
- ☒ Response to Office Action (19 pages)
- ☒ Amendment Transmittal Letter (in duplicate) (2 pages)
- ☒ Express Mail No. EV 889 010 445 US
- ☒ Certificate of Mailing
- ☒ Statement of Common Ownership (1 page)
- ☐ Other:

#210189.1

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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	10/750,139
Filing Date	June 3, 2004
First Named Inventor	Jessica R. DesNoyer
Group Art Unit	1618
Examiner Name	James William Rogers
Total Number of Pages in This Submission: 23	**Attorney Docket Number** 50623.326

ENCLOSURES *(check all that apply)*

- ☒ Deposit Account 07-1850 Authorization
- ☒ Postage Paid Return Postcard
- ☒ Amendment and Response to Office Action (19 pages)
  - ☒ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Petition for Extension of Time (__ month) (page) (in duplicate)
- ☐ Information Disclosure Statement with Form PTO-1449 citing ___ References
- ☒ Express Mail Label No. EV 889 010 445 US
- ☒ Certificate of Mailing
- ☒ Amendment Transmittal Letter (1 page) (in duplicate)
- ☐ Assignment Papers *(for an Application)*
- ☐ Drawing(s) Formal ___ Sheets with Submission of Formal
- ☐ Issue Fee Transmittal with PTO-85b (in duplicate)
- ☐ Request for Continued Examination Transmittal (RCE)
- ☐ Fee Transmittal Form (in duplicate)
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer (page)
- ☒ Statement of Common Ownership (1 page)
- ☐ CD, Number of CD(s) ____
- ☐ After Allowance Communication to Group
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to Group *(Appeal Notice, Brief, Reply Brief)*
- ☐ Proprietary Information
- ☐ Request for Status of Application
- ☐ Other Enclosure(s) *(please identify below)*:

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm *or* Individual name	Squire, Sanders & Dempsey L.L.P. Zhaoyang Li, Ph.D., Reg. No. 46,872
Signature	
Date	February 12, 2007

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date below:

Typed or printed name	Yayoi Barrack		
Signature		Date	February 12, 2007

Express Mail No. EV 889 010 445 US

Attorney Docket No.: 50623.326

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application Of: Examiner: Rogers, James William

Jessica R. DesNoyer et al. Art Unit: 1618

Serial No: 10/750,139

Filed: June 3, 2004

For: Poly(Ester Amide) Coating Composition For Implantable Devices

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Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

STATEMENT OF COMMON OWNERSHIP

Dear Examiner Rogers:

At the time the inventions of the current application (USSN 10/750,139) were made, the inventions of the current application and Pacetti (WO 03/022323) were owned by, or subject to an obligation of assignment to, Advanced Cardiovascular Systems, Inc., a California corporation.

Date: February 12, 2007

Respectfully submitted,

Zhaoyang Li, Ph.D.
Attorney for Applicants
Reg. No. 6,872

Squire, Sanders & Dempsey L.L.P.
One Maritime Plaza, Suite 300
San Francisco, CA 94111
Telephone (415) 954-0323
Facsimile (415) 393-9887

Express Mail Label No. EV 889 010 445 US

AMENDMENT TRANSMITTAL LETTER (Large Entity) Applicant(s): Jessica R. DesNoyer et al.			Docket No. **50623.326**
Serial No. **10/750,139**	Filing Date **June 3, 2004**	Examiner **James William Rogers**	Group Art Unit **1618**

Invention:

Poly(Ester Amide) Coating Composition For Implantable Devices

TO THE COMMISSIONER FOR PATENTS:

Transmitted herewith is an amendment in the above-identified application.

The fee has been calculated and is transmitted as show below.

CLAIMS AS AMENDED

	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST # PREV. PAID FOR	NUMBER EXTRA CLAIMS PRESENT	RATE	ADDITIONAL FEE
TOTAL CLAIMS	73	73	0	X $50.00	$00.00
INDEP. CLAIMS	6	6	0	X $200.00	$00.00
Multiple Dependent Claims (check if applicable) ☐					$00.00
				TOTAL ADDITIONAL FEE FOR THIS AMENDMENT	$00.00

☒ No additional fee is required for amendment.

☐ Please charge Deposit Account No. **07-1850** in the amount of **$0.00**

A duplicate copy of this sheet is enclosed.

☐ A check in the amount of _____ to cover the filing fee is enclosed.

☒ The Commissioner is hereby authorized to charge payment of any necessary fees associated with this communication or credit any overpayment to Deposit Account No. **07-1850.**

A duplicate copy of this sheet is enclosed.

☐ Any additional filing fees required under 37 C.F.R. 1.16.

☐ Any patent application processing fees under 37 C.F.R. 1.17.

Dated: February 12, 2007

Squire, Sanders & Dempsey L.L.P.
1 Maritime Plaza, Suite 300
San Francisco, CA 94111
(415) 954-0200

Zhaoyang Li, Ph.D.
Reg. No. 46,872

cc: Docket:

Express Mail Label No. EV 889 010 445 US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	DesNoyer et al.	Examiner:	James William Rogers
Serial No.:	10/750,139	Art Unit:	1618
Filed:	June 3, 2004		

Title: Poly(Ester Amide) Coating Composition For Implantable Devices

Mail Stop: AF
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

RESPONSE TO FINAL OFFICE ACTION

Dear Examiner Rogers:

This communication responds to the Final Office Action mailed on December 27, 2006.

Accompanying this communication is a Statement of Common Ownership.

In the claims

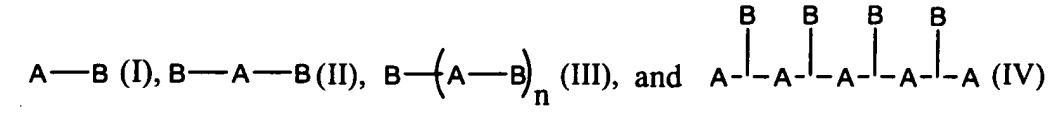
1. (Original) A method for forming a poly(ester amide) (PEA) coating with enhanced mechanical and release rate properties, comprising:

applying to an implantable device a solution or suspension of a composition comprising PEA and a low surface energy, surface blooming polymer, and

forming a coating on the implantable device comprising PEA and the low surface energy, surface blooming polymer.

2. (Previously presented) The method of claim 1 wherein the low surface energy, surface blooming polymer is selected from the group consisting of a block copolymer comprising a block miscible with the PEA and a hydrophobic block, a polymer comprising a backbone miscible with PEA and hydrophobic pendant groups, and a combination thereof.

3. (Original) The method of claim 1 wherein the low surface energy polymer is selected from the group consisting of formulae I-IV of the following structure:



wherein A is a PEA miscible block or PEA miscible backbone, and

wherein B is selected from the group consisting of a surface blooming block and a surface blooming pendant group.

4. (Original) The method of claim 3 wherein A is selected from the group consisting of polyurethane, poly(ester-urea) urethane, polyglycol, poly(tetramethylene glycol), poly(propylene glycol), polycaprolactone, ethylene vinyl alcohol copolymer, poly(butyl methacrylate), poly(methacrylate), poly(acrylate), poly(ether-urethane), poly(ester-urethane), poly(carbonate-urethane), poly(silicone-urethane), poly(urea-urethane), poly(glycolide), poly(L-latide), poly(l-lactide-co-glycolide), poly(D,L-lactide), poly(D,L-lactide-co-glycolide), poly(D,L-lactide-co-L-lactide), poly(glycolide-co-caprolactone), poly(D,L-lactide-co-caprolactone), poly(L-lactide-co-caprolactone), poly(dioxanone), poly(trimethylene carbonate), poly(trimethylene carbonate) copolymers, poly(3-hydroxybutyrate), poly(3-hydroxyvalerate), poly(4-hydroxybutyrate), poly(3-hydroxybutyrate-co-3-hydroxyvalerate), styrene-butadiene-styrene block copolymer, styrene-butylene/ethylene-styrene block copolymer, styrene-isobutylene-styrene triblock copolymer, poly(ethylene-co-vinyl acetate), and a combination thereof; and

wherein B is selected from the group consisting of a linear or branched alkyl chain, polysilanes, polysiloxanes, poly(dimethylsiloxane), a linear or branched perfluoro chain, and a combination thereof.

5. (Original) The method of claim 1 wherein the low surface energy polymer is selected from the group consisting of organosilicone surfactants, block copolymers of alkyl chains with polyglycol chains, fluoro surfactants, block copolymers of polydimethylsiloxane and polycaprolactone, polyurethanes end-capped with long chain perfluoro alcohols, poly(ester-urea)urethanes end-capped with long chain perfluoroalcohols, polyurethanes end-capped with

alkyl chains, polyurethanes end-capped with polydimethylsiloxane, copolymers of polycaprolactone and fluoroalcohols, and combinations thereof.

6. (Original) The method of any of claims 1-5 wherein the composition further comprises a bioactive agent.

7. (Original) The method of claim 6 wherein the bioactive agent is selected from the group consisting of Everolimus, paclitaxel, docetaxel, estradiol, steroidal anti-inflammatory agents, antibiotics, anticancer agents, nitric oxide donors, super oxide dismutases, super oxide dismutases mimics, 4-amino-2,2,6,6-tetramethylpiperidine-1-oxyl (4-amino-TEMPO), ABT-578, tacrolimus, pimecrolimus, batimastat, mycophenolic acid, clobetasol, dexamethasone, rapamycin, 40-*O*-(3-hydroxy)propyl-rapamycin, 40-*O*-[2-(2-hydroxy)ethoxy]ethyl-rapamycin, or 40-*O*-tetrazole-rapamycin, antiproliferative agents, non-steroidal anti-inflammatory agents, immunosuppressive agents, antimigratory agents, and a combination thereof.

8. (Original) A method for forming a poly(ester amide) (PEA) coating with enhanced mechanical and release rate properties, comprising:

applying to an implantable device a solution or suspension of a composition comprising PEA and at least one low surface energy polymer additive, and

forming a coating on the implantable device comprising PEA and the at least one low surface energy polymer additive.

9. (Original) The method of claim 8 wherein the at least one low surface energy polymer additive is selected from the group consisting of Teflon (poly(tetrafluoroethylene), FEP

(fluorinated ethylene-propylene), poly(tetrafluoroethylene-co-hexafluoropropene), PVDF (polyvinylidene fluoride), poly(fluoroalkenes), polysilanes, polysiloxanes, silicone (polydimethylsiloxane), hydrocarbon polymers, polyethylene, polypropylene, polystyrene, polybutadiene and combinations thereof.

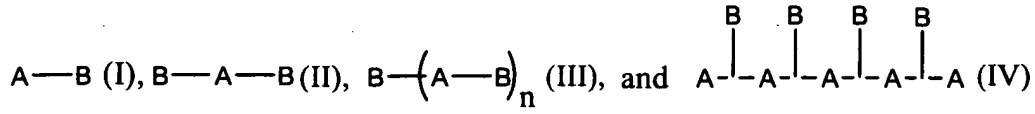
10. (Original) The method of claims 8 or 9 wherein the composition further comprises a bioactive agent.

11. (Original) The method of claim 10 wherein the bioactive agent is selected from the group consisting of Everolimus, paclitaxel, docetaxel, estradiol, steroidal anti-inflammatory agents, antibiotics, anticancer agents, nitric oxide donors, super oxide dismutases, super oxide dismutases mimics, 4-amino-2,2,6,6-tetramethylpiperidine-1-oxyl (4-amino-TEMPO), ABT-578, tacrolimus, pimecrolimus, batimastat, mycophenolic acid, clobetasol, dexamethasone, rapamycin, 40-*O*-(3-hydroxy)propyl-rapamycin, 40-*O*-[2-(2-hydroxy)ethoxy]ethyl-rapamycin, or 40-*O*-tetrazole-rapamycin, antiproliferative agents, non-steroidal anti-inflammatory agents, immunosuppressive agents, antimigratory agents, and a combination thereof.

12. (Original) A coating composition for coating an implantable device comprising poly(ester amide) (PEA) and a low surface energy, surface blooming polymer.

13. (Previously presented) The composition of claim 13 wherein the low surface energy, surface blooming polymer is selected from the group consisting of a block copolymer comprising a block miscible with the PEA and a hydrophobic block, a polymer comprising a backbone miscible with PEA and hydrophobic pendant groups, and a combination thereof.

14. (Original) The composition of claim 12 wherein the low surface energy, surface blooming polymer is selected from the group consisting of formulae I-IV of the following structure:



wherein A is a PEA miscible block or PEA miscible backbone, and

wherein B is selected from the group consisting of a surface blooming block and a surface blooming pendant group.

15. (Original) The composition of claim 14 wherein A is selected from the group consisting of polyurethane, poly(ester-urea) urethane, polyglycol, poly(tetramethylene glycol), poly(propylene glycol), polycaprolactone, ethylene vinyl alcohol copolymer, poly(butyl methacrylate), poly(methacrylate), poly(acrylate), and a combination thereof; and

wherein B is selected from the group consisting of a linear or branched alkyl chain, polysilanes, polysiloxanes, poly(dimethylsiloxane), a linear or branched perfluoro chain, and a combination thereof.

16. (Original) The composition of claim 15 wherein the low surface energy, surface blooming polymer is selected from the group consisting of organosilicone surfactants, block copolymers of alkyl chains with polyglycol chains, fluoro surfactants, block copolymers of polydimethylsiloxane and polycaprolactone, polyurethanes endcapped with long chain perfluoro alcohols, poly(ester-urea)urethanes endcapped with long chain perfluoro alcohols, polyurethanes

endcapped with alkyl chains, polyurethanes endcapped with polydimethylsiloxane, and combinations thereof.

17. (Original) The composition of any of claims 12-16 further comprising a bioactive agent.

18. (Original) The composition of claim 17 wherein the bioactive agent is selected from the group consisting of Everolimus, paclitaxel, docetaxel, estradiol, steroidal anti-inflammatory agents, antibiotics, anticancer agents, nitric oxide donors, super oxide dismutases, super oxide dismutases mimics, 4-amino-2,2,6,6-tetramethylpiperidine-1-oxyl (4-amino-TEMPO), ABT-578, tacrolimus, pimecrolimus, batimastat, mycophenolic acid, clobetasol, dexamethasone, rapamycin, 40-*O*-(3-hydroxy)propyl-rapamycin, 40-*O*-[2-(2-hydroxy)ethoxy]ethyl-rapamycin, or 40-*O*-tetrazole-rapamycin, antiproliferative agents, non-steroidal anti-inflammatory agents, immunosuppressive agents, antimigratory agents, and a combination thereof.

19. (Original) A coating composition for coating an implantable device comprising poly(ester amide) (PEA) and at least one low surface energy polymer additive.

20. (Original) The composition of claim 19 wherein the at least one low surface energy polymer additive is selected from the group consisting of Teflon (poly(tetrafluoroethylene), FEP (fluorinated ethylene-propylene), poly(tetrafluoroethylene-co-hexafluoropropene), PVDF (polyvinylidene fluoride), poly(fluoroalkenes), polysilanes, polysiloxanes, silicone (polydimethylsiloxane), hydrocarbon polymers, polyethylene, polypropylene, polystyrene, polybutadiene and combinations thereof.

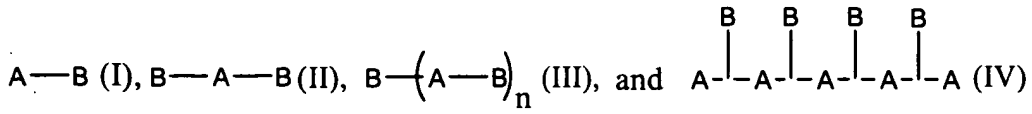
21. (Original) The composition of claims 19 or 20 further comprising a bioactive agent.

22. (Original) The composition of claim 21 wherein the bioactive agent is selected from the group consisting of Everolimus, paclitaxel, docetaxel, estradiol, steroidal anti-inflammatory agents, antibiotics, anticancer agents, nitric oxide donors, super oxide dismutases, super oxide dismutases mimics, 4-amino-2,2,6,6-tetramethylpiperidine-1-oxyl (4-amino-TEMPO), ABT-578, tacrolimus, pimecrolimus, batimastat, mycophenolic acid, clobetasol, dexamethasone, rapamycin, 40-*O*-(3-hydroxy)propyl-rapamycin, 40-*O*-[2-(2-hydroxy)ethoxy]ethyl-rapamycin, or 40-*O*-tetrazole-rapamycin, antiproliferative agents, non-steroidal anti-inflammatory agents, immunosuppressive agents, antimigratory agents, and a combination thereof.

23. (Original) An implantable device comprising a coating which comprises a poly(ester amide) (PEA) and a low surface energy, surface blooming polymer.

24. (Previously presented) The implantable device of claim 23 wherein the low surface energy, surface blooming polymer is selected from the group consisting of a block copolymer comprising a block miscible with the PEA and a hydrophobic block, a polymer comprising a backbone miscible with PEA and hydrophobic pendant groups, and a combination thereof.

25. (Original) The implantable device of claim 24 wherein the low surface energy, surface blooming polymer is selected from the group consisting of formulae I-IV of the following structure:



wherein A is a PEA miscible block or PEA miscible backbone, and

wherein B is selected from the group consisting of a surface blooming block and a surface blooming pendant group.

26. (Original) The implantable device of claim 25 wherein A is selected from the group consisting of polyurethane, poly(ester-urea) urethane, polyglycol, poly(tetramethylene glycol), poly(propylene glycol), polycaprolactone, ethylene vinyl alcohol copolymer, poly(butyl methacrylate), poly(methacrylate), poly(acrylate), and a combination thereof; and

wherein B is selected from the group consisting of a linear or branched alkyl chain, polysilanes, polysiloxanes, poly(dimethylsiloxane), a linear or branched perfluoro chain, and a combination thereof.

27. (Original) The implantable device of claim 26 wherein the low surface energy, surface blooming polymer is selected from the group consisting of organosilicone surfactants, block copolymers of alkyl chains with polyglycol chains, fluoro surfactants, block copolymers of polydimethylsiloxane and polycaprolactone, polyurethanes endcapped with long chain perfluoro alcohols, poly(ester-urea)urethanes endcapped with long chain perfluoro alcohols, polyurethanes endcapped with alkyl chains, polyurethanes endcapped with polydimethylsiloxane, and combinations thereof.

28. (Original) The implantable device of any of claims 23-27 further comprising a bioactive agent.

29. (Original) The implantable device of claim 28 wherein the bioactive agent is selected from the group consisting of Everolimus, paclitaxel, docetaxel, estradiol, steroidal anti-inflammatory agents, antibiotics, anticancer agents, nitric oxide donors, super oxide dismutases, super oxide dismutases mimics, 4-amino-2,2,6,6-tetramethylpiperidine-1-oxyl (4-amino-TEMPO), ABT-578, tacrolimus, pimecrolimus, batimastat, mycophenolic acid, clobetasol, dexamethasone, rapamycin, 40-*O*-(3-hydroxy)propyl-rapamycin, 40-*O*-[2-(2-hydroxy)ethoxy]ethyl-rapamycin, or 40-*O*-tetrazole-rapamycin, antiproliferative agents, non-steroidal anti-inflammatory agents, immunosuppressive agents, antimigratory agents, and a combination thereof.

30. (Original) An implantable device comprising a coating which comprises poly(ester amide) (PEA) and at least one low surface energy polymer additive.

31. (Original) The implantable device of claim 30 wherein the at least one low surface energy polymer additive is selected from the group consisting of Teflon (poly(tetrafluoroethylene), FEP (fluorinated ethylene-propylene), poly(tetrafluoroethylene-co-hexafluoropropene), PVDF (polyvinylidene fluoride), poly(fluoroalkenes), polysilanes, polysiloxanes, silicone (polydimethylsiloxane), hydrocarbon polymers, polyethylene, polypropylene, polystyrene, polybutadiene and combinations thereof.

32. (Original) The implantable device of claims 30 or 31 further comprising a bioactive agent.

33. (Original) The implantable device of claim 32 wherein the bioactive agent is selected from the group consisting of Everolimus, paclitaxel, docetaxel, estradiol, steroidal anti-inflammatory agents, antibiotics, anticancer agents, nitric oxide donors, super oxide dismutases, super oxide dismutases mimics, 4-amino-2,2,6,6-tetramethylpiperidine-1-oxyl (4-amino-TEMPO), ABT-578, tacrolimus, pimecrolimus, batimastat, mycophenolic acid, clobetasol, dexamethasone, rapamycin, 40-*O*-(3-hydroxy)propyl-rapamycin, 40-*O*-[2-(2-hydroxy)ethoxy]ethyl-rapamycin, or 40-*O*-tetrazole-rapamycin, antiproliferative agents, non-steroidal anti-inflammatory agents, immunosuppressive agents, antimigratory agents, and a combination thereof.

34. (Original) The implantable device of claim 23 which is a stent.

35. (Original) The implantable device of claim 24 which is a stent.

36. (Original) The implantable device of claim 25 which is a stent.

37. (Original) The implantable device of claim 26 which is a stent.

38. (Original) The implantable device of claim 27 which is a stent.

39. (Original) The implantable device of claim 30 which is a stent.

40. (Original) The implantable device of claim 31 which is a stent.

41. (Original) The implantable device of claim 28 which is a drug-eluting stent.

42. (Original) The implantable device of claim 29 which is a drug-eluting stent.

43. (Original) The implantable device of claim 32 which is a drug-eluting stent.

44. (Original) The implantable device of claim 33 which is a drug-eluting stent.

45. (Original) A method of treating a disorder in a human being by implanting in the human being a stent as defined in claim 34,

wherein the disorder is selected from the group consisting of atherosclerosis, thrombosis, restenosis, hemorrhage, vascular dissection or perforation, vascular aneurysm, vulnerable plaque, chronic total occlusion, claudication, anastomotic proliferation for vein and artificial grafts, bile duct obstruction, ureter obstruction, tumor obstruction, and combinations thereof.

46. (Original) A method of treating a disorder in a human being by implanting in the human being a stent as defined in claim 35,

wherein the disorder is selected from the group consisting of atherosclerosis, thrombosis, restenosis, hemorrhage, vascular dissection or perforation, vascular aneurysm, vulnerable plaque, chronic total occlusion, claudication, anastomotic proliferation for vein and artificial grafts, bile duct obstruction, ureter obstruction, tumor obstruction, and combinations thereof.

47. (Original) A method of treating a disorder in a human being by implanting in the human being a stent as defined in claim 36,

wherein the disorder is selected from the group consisting of atherosclerosis, thrombosis, restenosis, hemorrhage, vascular dissection or perforation, vascular aneurysm, vulnerable plaque, chronic total occlusion, claudication, anastomotic proliferation for vein and artificial grafts, bile duct obstruction, ureter obstruction, tumor obstruction, and combinations thereof.

48. (Original) A method of treating a disorder in a human being by implanting in the human being a stent as defined in claim 37,

wherein the disorder is selected from the group consisting of atherosclerosis, thrombosis, restenosis, hemorrhage, vascular dissection or perforation, vascular aneurysm, vulnerable plaque, chronic total occlusion, claudication, anastomotic proliferation for vein and artificial grafts, bile duct obstruction, ureter obstruction, tumor obstruction, and combinations thereof.

49. (Original) A method of treating a disorder in a human being by implanting in the human being a stent as defined in claim 38,

wherein the disorder is selected from the group consisting of atherosclerosis, thrombosis, restenosis, hemorrhage, vascular dissection or perforation, vascular aneurysm, vulnerable plaque, chronic total occlusion, claudication, anastomotic proliferation for vein and artificial grafts, bile duct obstruction, ureter obstruction, tumor obstruction, and combinations thereof.

50. (Original) A method of treating a disorder in a human being by implanting in the human being a stent as defined in claim 39,

wherein the disorder is selected from the group consisting of atherosclerosis, thrombosis, restenosis, hemorrhage, vascular dissection or perforation, vascular aneurysm, vulnerable plaque, chronic total occlusion, claudication, anastomotic proliferation for vein and artificial grafts, bile duct obstruction, ureter obstruction, tumor obstruction, and combinations thereof.

51. (Original) A method of treating a disorder in a human being by implanting in the human being a stent as defined in claim 42,

wherein the disorder is selected from the group consisting of atherosclerosis, thrombosis, restenosis, hemorrhage, vascular dissection or perforation, vascular aneurysm, vulnerable plaque, chronic total occlusion, claudication, anastomotic proliferation for vein and artificial grafts, bile duct obstruction, ureter obstruction, tumor obstruction, and combinations thereof.

52. (Original) A method of treating a disorder in a human being by implanting in the human being a stent as defined in claim 44,

wherein the disorder is selected from the group consisting of atherosclerosis, thrombosis, restenosis, hemorrhage, vascular dissection or perforation, vascular aneurysm, vulnerable plaque, chronic total occlusion, claudication, anastomotic proliferation for vein and artificial grafts, bile duct obstruction, ureter obstruction, tumor obstruction, and combinations thereof.

53. (Previously presented) The method of claim 1, wherein the coating is biologically benign.

54. (Previously presented) The method of claim 8, wherein the coating is biologically benign.

55. (Previously presented) The coating of claim 12, which is biologically benign.

56. (Previously presented) The coating of claim 19, which is biologically benign.

57. (Previously presented) The implantable device of claim 23, wherein the coating is biologically benign.

58. (Previously presented) The implantable device of claim 30, wherein the coating is biologically benign.

Remarks

Claims 1-58 are pending. Claims 1-52 are rejected.

Information Disclosure Statement

Applicants filed Information Disclosure Statements (IDSs) on May 6, 2004, July 28, 2005, November 2, 2006 and December 27, 2006, respectively. However, the IDSs filed on May 6, 2004, and December 27, 2006 have not been returned to the Applicants. Applicants respectfully request the Examiner to sign off and return to Applicants these IDSs.

Rejections under 35 U.S.C. § 103

Claims 1-58 are rejected under 35 U.S.C. §103(a) as being obvious over WO 03/022323 A1 by Pacetti et al. ("Pacetti") in view of WO 98/32398 A1 by Roby et al. ("Roby").

Pacetti, assigned to Advanced Cardiovascular Systems, Inc. ("ACS") at the time of filing the application, has the same ownership as the present application when filed. A statement of an attorney of record can be sufficient evidence to establish common ownership. As established by the enclosed Statement of Common Ownership, at the time the inventions of the current application were made, the inventions of the present application and Millare were owned by or subject to an obligation of assignment to ACS. Therefore Pacetti and the present application are commonly owned by ACS. **This disqualifies Pacetti as a 35 U.S.C. 103 art reference against the present application**.

Roby describes the preparation of a poly(ester amide) (PEA) polymer that can be used for fabrication of surgical devices. However, there is no teaching or description in Roby of a coating comprising a composition that includes a PEA polymer and a low surface energy, surface blooming polymer.

Claim 1 defines a method of forming a coating having a poly(ester amide) (PEA) polymer and a low surface energy, surface blooming polymer, which Roby fails to describe or teach. Therefore, claim 1 is patentably allowable over Roby. Claims 2-7 and 53 depend from claim 1 and are patentable over Roby for at least the same reason.

Claim 8 defines a method of forming a coating having a PEA polymer and at least one low surface energy polymer additive. Roby fails to describe or teach this element. Therefore, claim 8 is patentably allowable over Roby. Claims 9-11 and 54 depend from claim 8 and are patentable over Roby for at least the same reason.

Claim 12 defines a coating having a PEA polymer and at least one low surface energy polymer. Roby fails to describe or teach this element. Therefore, claim 12 is patentably allowable over Roby. Claims 13-18 and 55 depend from claim 12 and are patentable over Roby for at least the same reason.

Claim 19 defines a coating having a PEA polymer and at least one low surface energy polymer additive. Roby fails to describe or teach this element. Therefore, claim 19 is patentably allowable over Roby. Claims 20-22 and 56 depend from claim 19 and are patentable over Roby for at least the same reason.

Claim 23 defines a medical device comprising a coating having a PEA polymer and at least one low surface energy polymer. Roby fails to describe or teach this element. Therefore, claim 23 is patentably allowable over Roby. Claims 24-29, 34-38, 41, 42, 45-49, 51 and 57 depend from claim 23 and are patentable over Roby for at least the same reason.

Claim 30 defines a medical device comprising a coating having a PEA polymer and at least one low surface energy polymer additive. Roby fails to describe or teach this element.

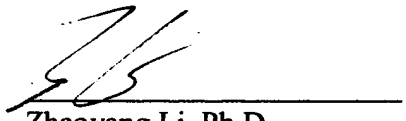
Therefore, claim 30 is patentably allowable over Roby. Claims 31-33, 39, 40, 43, 44, 50, 52 and 58 depend from claim 30 and are patentable over Roby for at least the same reason.

The undersigned authorizes the examiner to charge any fees that may be required or credit of any overpayment to be made to Deposit Account No. 07-1850.

Withdrawal of the rejection and allowance of the claims are respectfully requested. **If the Examiner has any suggestions or amendments to the claims to place the claims in condition for allowance, applicant would prefer a telephone call to the undersigned attorney for approval of an Examiner's amendment.** If the Examiner has any questions or concerns, the Examiner is invited to telephone the undersigned attorney at (415) 393-9885.

Date: February 12, 2007
Squire, Sanders & Dempsey L.L.P.
One Maritime Plaza, Suite 300
San Francisco, CA 94111
Telephone (415) 393-9885
Facsimile (415) 393-9887

Respectfully submitted,



Zhaoyang Li, Ph.D.
Reg. No. 46,872

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,139	06/03/2004	Jessica R. DesNoyer	50623.326	2159

7590 03/16/2007

Squire, Sanders & Dempsey, L.L.P.
Suite 300
1 Maritime Plaza
San Francisco, CA 94111

ADVISORY ACTION

RESPONSE DUE: 3/27/07
w/w 1 MONTH EXT: 4/27/07
w/w/ 2 MONTH EXT: 5/27/07
DROP DEAD DATE: 6/27/07

EXAMINER	
ROGERS, JAMES WILLIAM	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
03/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

DOCKETED: _____

MAR 19 2007

BY: tjb Atty: PL

SQUIRE, SANDERS & DEMPSEY

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/750,139	Applicant(s) DESNOYER ET AL.	
	Examiner James W. Rogers, Ph.D.	Art Unit 1618	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 13 February 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: _____.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

Continuation of 11. does NOT place the application in condition for allowance because: The Pacetti patent was published more than 1 year before applicants earliest filling date, this qualifies the art as having a 102(b) date. Therefore since the reference has a 102(b) date applicants cannot argue common assignment to the Pacetti reference. See MPEP § 706.02 (j) and 706.02(l)(2) for information pertaining to establishing prior art exclusions due to common ownership or joint research agreements and for contents of a 35 U.S.C. 103 rejection.

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER

Date Mailed: March 22, 2007	By: ZL/yb	Docket No.: 50623.326
Serial No.: 10/750,139		Filed: June 3, 2004
Applicant: Jessica Reneé DesNoyer et al.		
Title: Poly(ester amide) Coating Composition for Implantable Devices		

The following has been received in the U.S. Patent Office on the date stamped hereon:

- ☒ Transmittal Form (1 page)
- ☒ Deposit Account Authorization 07-1850
- ☒ Response to Advisory Action (18 pages)
- ☒ Request for Continued Examination Transmittal (RCE) (in duplicate) (2 pages)
- ☒ Fee Transmittal Form (in duplicate) (in duplicate) (2 pages)
- ☒ Express Mail No. EV 889 011 012 US
- ☒ Certificate of Mailing
- ☐ Statement of Common Ownership (page)
- ☐ Amendment Transmittal Letter (in duplicate) (pages)
- ☐ Other:

#214373.1

Date Mailed: March 22, 2007	By: ZL/yb	Docket No.: 50623.326
Serial No.: 10/750,139		Filed: June 3, 2004
Applicant: Jessica Reneé DesNoyer et al.		
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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission	23

Application Number	10/750,139
Filing Date	June 3, 2004
First Named Inventor	Jessica R. DesNoyer
Group Art Unit	1618
Examiner Name	James William Rogers
Attorney Docket Number	50623.326

ENCLOSURES *(check all that apply)*

- ☒ Deposit Account 07-1850 Authorization
- ☒ Postage Paid Return Postcard
- ☒ Response to Advisory Action (18 pages)
  - ☒ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Petition for Extension of Time (__ month) (page) (in duplicate)
- ☐ Information Disclosure Statement with Form PTO-1449 citing ___ References
- ☒ Express Mail Label No. EV 889 011 012 US
- ☒ Certificate of Mailing
- ☐ Amendment Transmittal Letter (1 page) (in duplicate)
- ☐ Assignment Papers *(for an Application)*
- ☐ Drawing(s) Formal ___ Sheets with Submission of Formal
- ☐ Issue Fee Transmittal with PTO-85b (in duplicate)
- ☒ Request for Continued Examination Transmittal (RCE) (in duplicate) (2 pages)
- ☒ Fee Transmittal Form (in duplicate) (in duplicate) (2 pages)
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer (page)
- ☐ Statement of Common Ownership (page)
- ☐ CD, Number of CD(s) ____
- ☐ After Allowance Communication to Group
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to Group *(Appeal Notice, Brief, Reply Brief)*
- ☐ Proprietary Information
- ☐ Request for Status of Application
- ☐ Other Enclosure(s) *(please identify below)*:

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	Squire, Sanders & Dempsey L.L.P. Zhaoyang Li, Ph.D., Reg. No. 46,872
Signature	
Date	March 22, 2007

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date below:

Typed or printed name	Yayoi Barrack		
Signature		Date	March 22, 2007

FEE TRANSMITTAL for FY 2007

Effective 10/01/2004. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 790.00

Complete if Known	
Application Number	10/750,139
Filing Date	June 3, 2004
First Named Inventor	Jessica R. DesNoyer
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Art Unit	1618
Attorney Docket No.	50623.326

METHOD OF PAYMENT *(check all that apply)*

☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☒ Deposit Account:

Deposit Account Number: 07-1850

Deposit Account Name: Squire, Sanders & Dempsey L.L.P.

The Director is authorized to: *(check all that apply)*
☒ Charge fee(s) indicated below ☒ Credit any overpayments
☒ Charge any additional fee(s) or any underpayment of fee(s)
☐ Charge fee(s) indicated below, **except for the filing fee** to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1001	300	2001	150	Utility filing fee	
1002	200	2002	100	Design filing fee	
1003	200	2003	100	Plant filing fee	
1004	300	2004	150	Reissue filing fee	
1005	200	2005	100	Provisional filing fee	

SUBTOTAL (1) ($)

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

			Extra Claims		Fee from below		Fee Paid
Total Claims	73	-73 **	= 0	X	50	=	0
Independent Claims	6	-6 **	= 0	X	200	=	0
Multiple Dependent				X		=	0

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
1202	50	2202	25	Claims in excess of 20
1201	200	2201	100	Independent claims in excess of 3
1203	360	2203	180	Multiple dependent claim, if not paid
1204	200	2204	100	** Reissue independent claims over original patent
1205	50	2205	25	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($) 0

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet.	
1053	130	1053	130	Non-English specification	
1801	790	2801	395	Request for continued examination (RCE)	790.00
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	430	2252	215	Extension for reply within second month	
1253	980	2253	490	Extension for reply within third month	
1254	1,530	2254	765	Extension for reply within fourth month	
1255	2,080	2255	1,040	Extension for reply within fifth month	
1401	340	2401	170	Notice of Appeal	
1402	340	2402	170	Filing a brief in support of an appeal	
1403	300	2403	150	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive – unavoidable	
1453	1,370	2453	685	Petition to revive – unintentional	
1501	1,370	2501	685	Utility issue fee (or reissue)	
1502	490	2502	245	Design issue fee	
1503	660	2503	330	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17 (q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	790	2809	395	Filing a submission after final rejection (37 CFR § 1.129(a))	
1810	790	2810	395	For each additional invention to be examined (37 CFR § 1.129(b))	
1801	790	2801	395	Request for Continued Examination (RCE)	
1311	200	2311	100	Patent Examination Fee	
				Other fee (specify)	

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) ($) 790.00

SUBMITTED BY

Complete *(if applicable)*

Name (Print/Type)	Zhaoyang Li, Ph.D.	Registration No. (Attorney/Agent)	46,872	Telephone	(415) 954-0200
Signature				Date	March 22, 2007

Via Express Mail No. EV 889 011 012 US

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PTO/SB/30 (09-06)
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REQUEST FOR CONTINUED EXAMINATION (RCE) TRANSMITTAL

Address to:
Commissioner for Patents
Mail Stop RCE
P.O. Box 1450
Alexandria, VA 22313-1450

Application Number	10/750,139
Filing Date	June 3, 2004
First Named Inventor	Jessica R. DesNoyer
Art Unit	1618
Examiner Name	James William Rogers
Attorney Docket Number	50623.326

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application. Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. See Instruction Sheet for RCEs (not to be submitted to the USPTO) on page 2.

1. Submission required under 37 C.F.R. 1.114

a. ☐ Previously submitted
   i. ☐ Consider the amendment(s)/reply under 37 C.F.R. 1.116 previously filed on
   (Any unentered amendment(s) referred to above will be entered).
   ii. ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
   iii. ☐ Other _____

b. ☒ Enclosed
   i. ☒ Amendment/Reply
   ii ☐ Affidavit(s)/Declaration(s)
   iii. ☐ Information Disclosure Statement (IDS)
   iv. ☐ Other _____

2.

a. ☐ Suspension of action on the above-identified application is requested under 37 C.F.R. 1.103(c) for a period of _____months. (Period of suspension shall not exceed 3 months; Fee under 37 C.F.R. 1.17(i) required)

b. ☐ Other _____

3. Fees The RCE fee under 37 C.F.R. 1.17(e) is required by 37 C.F.R. 1.114 when the RCE is filed.

a. ☒ The Director is hereby authorized to charge the following fees, or credit any overpayments, to Deposit Account No. 07-1850
   i. ☒ RCE fee required under 37 C.F.R. 1.17(e)
   ii. ☐ Extension of time fee (37 C.F.R. 1.136 and 1.17)
   iii. ☐ Other _____

b. ☐ Check in the amount of $ _____ enclosed

c. ☐ Payment by credit card (Form PTO-2038 enclosed

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

Name (Print /Type)	Zhaoyang Li, Ph.D.	*Registration No. (Attorney/Agent)*	46,872
Signature		*Date*	March 22, 2007

CERTIFICATE OF MAILING OR TRANSMISSION

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Name (Print /Type)	Yayoi Barrack		
Signature		*Date*	March 22, 2007

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Express Mail Label No. EV 889 011 012 US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	DesNoyer et al.	Examiner:	James William Rogers
Serial No.:	10/750,139	Art Unit:	1618
Filed:	June 3, 2004		
Title:	Poly(Ester Amide) Coating Composition For Implantable Devices		

Mail Stop: RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

RESPONSE TO ADVISORY ACTION

Dear Examiner Rogers:

This communication responds to the Final Office Action mailed on December 27, 2006 and the Advisory Action mailed on March 16, 2007. A Request for Continued Examination (RCE) is being submitted herewith.

In the claims

1. (Currently amended) A method for forming a poly(ester amide) (PEA) coating with enhanced mechanical and release rate properties, comprising:

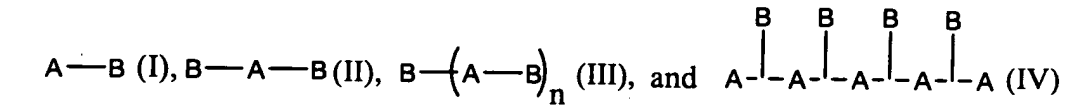
applying to an implantable device a solution or suspension of a composition comprising a PEA and a low surface energy, surface blooming polymer, and

forming a coating on the implantable device comprising PEA and the low surface energy, surface blooming polymer,

wherein the low surface energy, surface blooming polymer comprises a PEA miscible block or PEA miscible backbone.

2. (Previously presented) The method of claim 1 wherein the low surface energy, surface blooming polymer is selected from the group consisting of a block copolymer comprising a block miscible with the PEA and a hydrophobic block, a polymer comprising a backbone miscible with PEA and hydrophobic pendant groups, and a combination thereof.

3. (Original) The method of claim 1 wherein the low surface energy polymer is selected from the group consisting of formulae I-IV of the following structure:



wherein A is a PEA miscible block or PEA miscible backbone, and

wherein B is selected from the group consisting of a surface blooming block and a surface blooming pendant group.

4. (Original) The method of claim 3 wherein A is selected from the group consisting of polyurethane, poly(ester-urea) urethane, polyglycol, poly(tetramethylene glycol), poly(propylene glycol), polycaprolactone, ethylene vinyl alcohol copolymer, poly(butyl

methacrylate), poly(methacrylate), poly(acrylate), poly(ether-urethane), poly(ester-urethane), poly(carbonate-urethane), poly(silicone-urethane), poly(urea-urethane), poly(glycolide), poly(L-latide), poly(l-lactide-co-glycolide), poly(D,L-lactide), poly(D,L-lactide-co-glycolide), poly(D,L-lactide-co-L-lactide), poly(glycolide-co-caprolactone), poly(D,L-lactide-co-caprolactone), poly(L-lactide-co-caprolactone), poly(dioxanone), poly(trimethylene carbonate), poly(trimethylene carbonate) copolymers, poly(3-hydroxybutyrate), poly(3-hydroxyvalerate), poly(4-hydroxybutyrate), poly(3-hydroxybutyrate-co-3-hydroxyvalerate), styrene-butadiene-styrene block copolymer, styrene-butylene/ethylene-styrene block copolymer, styrene-isobutylene-styrene triblock copolymer, poly(ethylene-co-vinyl acetate), and a combination thereof; and

wherein B is selected from the group consisting of a linear or branched alkyl chain, polysilanes, polysiloxanes, poly(dimethylsiloxane), a linear or branched perfluoro chain, and a combination thereof.

5. (Original) The method of claim 1 wherein the low surface energy polymer is selected from the group consisting of organosilicone surfactants, block copolymers of alkyl chains with polyglycol chains, fluoro surfactants, block copolymers of polydimethylsiloxane and polycaprolactone, polyurethanes end-capped with long chain perfluoro alcohols, poly(ester-urea)urethanes end-capped with long chain perfluoroalcohols, polyurethanes end-capped with alkyl chains, polyurethanes end-capped with polydimethylsiloxane, copolymers of polycaprolactone and fluoroalcohols, and combinations thereof.

6. (Original) The method of any of claims 1-5 wherein the composition further comprises a bioactive agent.

7. (Original) The method of claim 6 wherein the bioactive agent is selected from the group consisting of Everolimus, paclitaxel, docetaxel, estradiol, steroidal anti-inflammatory agents, antibiotics, anticancer agents, nitric oxide donors, super oxide dismutases, super oxide dismutases mimics, 4-amino-2,2,6,6-tetramethylpiperidine-1-oxyl (4-amino-TEMPO), ABT-578, tacrolimus, pimecrolimus, batimastat, mycophenolic acid, clobetasol, dexamethasone, rapamycin, 40-*O*-(3-hydroxy)propyl-rapamycin, 40-*O*-[2-(2-hydroxy)ethoxy]ethyl-rapamycin, or 40-*O*-tetrazole-rapamycin, antiproliferative agents, non-steroidal anti-inflammatory agents, immunosuppressive agents, antimigratory agents, and a combination thereof.

8. (Currently amended) A method for forming a poly(ester amide) (PEA) coating with enhanced mechanical and release rate properties, comprising:

applying to an implantable device a solution or suspension of a composition comprising a PEA and at least one low surface energy polymer additive, and

forming a coating on the implantable device comprising PEA and the at least one low surface energy polymer additive,

wherein the at least one low surface energy polymer additive comprises a PEA miscible block or PEA miscible backbone.

9. (Original) The method of claim 8 wherein the at least one low surface energy polymer additive is selected from the group consisting of Teflon (poly(tetrafluoroethylene), FEP (fluorinated ethylene-propylene), poly(tetrafluoroethylene-co-hexafluoropropene), PVDF (polyvinylidene fluoride), poly(fluoroalkenes), polysilanes, polysiloxanes, silicone (polydimethylsiloxane), hydrocarbon polymers, polyethylene, polypropylene, polystyrene, polybutadiene and combinations thereof.

10. (Original) The method of claims 8 or 9 wherein the composition further comprises a bioactive agent.

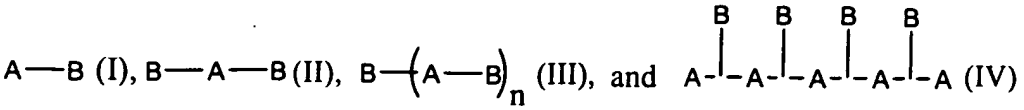
11. (Original) The method of claim 10 wherein the bioactive agent is selected from the group consisting of Everolimus, paclitaxel, docetaxel, estradiol, steroidal anti-inflammatory agents, antibiotics, anticancer agents, nitric oxide donors, super oxide dismutases, super oxide dismutases mimics, 4-amino-2,2,6,6-tetramethylpiperidine-1-oxyl (4-amino-TEMPO), ABT-578, tacrolimus, pimecrolimus, batimastat, mycophenolic acid, clobetasol, dexamethasone, rapamycin, 40-*O*-(3-hydroxy)propyl-rapamycin, 40-*O*-[2-(2-hydroxy)ethoxy]ethyl-rapamycin, or 40-*O*-tetrazole-rapamycin, antiproliferative agents, non-steroidal anti-inflammatory agents, immunosuppressive agents, antimigratory agents, and a combination thereof.

12. (Currently amended) A coating composition for coating an implantable device comprising a poly(ester amide) (PEA) and a low surface energy, surface blooming polymer,

wherein the low surface energy, surface blooming polymer comprises a PEA miscible block or PEA miscible backbone.

13. (Previously presented) The composition of claim 13 wherein the low surface energy, surface blooming polymer is selected from the group consisting of a block copolymer comprising a block miscible with the PEA and a hydrophobic block, a polymer comprising a backbone miscible with PEA and hydrophobic pendant groups, and a combination thereof.

14. (Original) The composition of claim 12 wherein the low surface energy, surface blooming polymer is selected from the group consisting of formulae I-IV of the following structure:



wherein A is a PEA miscible block or PEA miscible backbone, and

wherein B is selected from the group consisting of a surface blooming block and a surface blooming pendant group.

15. (Original) The composition of claim 14 wherein A is selected from the group consisting of polyurethane, poly(ester-urea) urethane, polyglycol, poly(tetramethylene glycol), poly(propylene glycol), polycaprolactone, ethylene vinyl alcohol copolymer, poly(butyl methacrylate), poly(methacrylate), poly(acrylate), and a combination thereof; and

wherein B is selected from the group consisting of a linear or branched alkyl chain, polysilanes, polysiloxanes, poly(dimethylsiloxane), a linear or branched perfluoro chain, and a combination thereof.

16. (Original) The composition of claim 15 wherein the low surface energy, surface blooming polymer is selected from the group consisting of organosilicone surfactants, block copolymers of alkyl chains with polyglycol chains, fluoro surfactants, block copolymers of polydimethylsiloxane and polycaprolactone, polyurethanes endcapped with long chain perfluoro alcohols, poly(ester-urea)urethanes endcapped with long chain perfluoro alcohols, polyurethanes endcapped with alkyl chains, polyurethanes endcapped with polydimethylsiloxane, and combinations thereof.

17. (Original) The composition of any of claims 12-16 further comprising a bioactive agent.

18. (Original) The composition of claim 17 wherein the bioactive agent is selected from the group consisting of Everolimus, paclitaxel, docetaxel, estradiol, steroidal anti-inflammatory agents, antibiotics, anticancer agents, nitric oxide donors, super oxide dismutases, super oxide dismutases mimics, 4-amino-2,2,6,6-tetramethylpiperidine-1-oxyl (4-amino-

TEMPO), ABT-578, tacrolimus, pimecrolimus, batimastat, mycophenolic acid, clobetasol, dexamethasone, rapamycin, 40-*O*-(3-hydroxy)propyl-rapamycin, 40-*O*-[2-(2-hydroxy)ethoxy]ethyl-rapamycin, or 40-*O*-tetrazole-rapamycin, antiproliferative agents, non-steroidal anti-inflammatory agents, immunosuppressive agents, antimigratory agents, and a combination thereof.

19. (Currently amended) A coating composition for coating an implantable device comprising a poly(ester amide) (PEA) and at least one low surface energy polymer additive, wherein the at least one low surface energy polymer additive comprises a PEA miscible block or PEA miscible backbone.

20. (Original) The composition of claim 19 wherein the at least one low surface energy polymer additive is selected from the group consisting of Teflon (poly(tetrafluoroethylene), FEP (fluorinated ethylene-propylene), poly(tetrafluoroethylene-co-hexafluoropropene), PVDF (polyvinylidene fluoride), poly(fluoroalkenes), polysilanes, polysiloxanes, silicone (polydimethylsiloxane), hydrocarbon polymers, polyethylene, polypropylene, polystyrene, polybutadiene and combinations thereof.

21. (Original) The composition of claims 19 or 20 further comprising a bioactive agent.

22. (Original) The composition of claim 21 wherein the bioactive agent is selected from the group consisting of Everolimus, paclitaxel, docetaxel, estradiol, steroidal anti-inflammatory agents, antibiotics, anticancer agents, nitric oxide donors, super oxide dismutases, super oxide dismutases mimics, 4-amino-2,2,6,6-tetramethylpiperidine-1-oxyl (4-amino-TEMPO), ABT-578, tacrolimus, pimecrolimus, batimastat, mycophenolic acid, clobetasol, dexamethasone, rapamycin, 40-*O*-(3-hydroxy)propyl-rapamycin, 40-*O*-[2-(2-

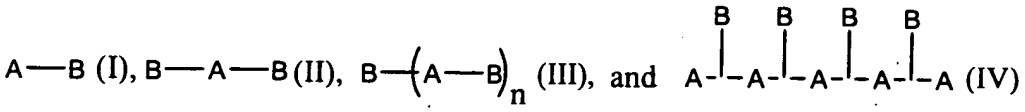
hydroxy)ethoxy]ethyl-rapamycin, or 40-*O*-tetrazole-rapamycin, antiproliferative agents, non-steroidal anti-inflammatory agents, immunosuppressive agents, antimigratory agents, and a combination thereof.

23. (Currently amended) An implantable device comprising a coating which comprises a poly(ester amide) (PEA) and a low surface energy, surface blooming polymer,

wherein the low surface energy, surface blooming polymer comprises a PEA miscible block or PEA miscible backbone.

24. (Previously presented) The implantable device of claim 23 wherein the low surface energy, surface blooming polymer is selected from the group consisting of a block copolymer comprising a block miscible with the PEA and a hydrophobic block, a polymer comprising a backbone miscible with PEA and hydrophobic pendant groups, and a combination thereof.

25. (Original) The implantable device of claim 24 wherein the low surface energy, surface blooming polymer is selected from the group consisting of formulae I-IV of the following structure:



wherein A is a PEA miscible block or PEA miscible backbone, and

wherein B is selected from the group consisting of a surface blooming block and a surface blooming pendant group.

26. (Original) The implantable device of claim 25 wherein A is selected from the group consisting of polyurethane, poly(ester-urea) urethane, polyglycol, poly(tetramethylene

glycol), poly(propylene glycol), polycaprolactone, ethylene vinyl alcohol copolymer, poly(butyl methacrylate), poly(methacrylate), poly(acrylate), and a combination thereof; and

wherein B is selected from the group consisting of a linear or branched alkyl chain, polysilanes, polysiloxanes, poly(dimethylsiloxane), a linear or branched perfluoro chain, and a combination thereof.

27. (Original) The implantable device of claim 26 wherein the low surface energy, surface blooming polymer is selected from the group consisting of organosilicone surfactants, block copolymers of alkyl chains with polyglycol chains, fluoro surfactants, block copolymers of polydimethylsiloxane and polycaprolactone, polyurethanes endcapped with long chain perfluoro alcohols, poly(ester-urea)urethanes endcapped with long chain perfluoro alcohols, polyurethanes endcapped with alkyl chains, polyurethanes endcapped with polydimethylsiloxane, and combinations thereof.

28. (Original) The implantable device of any of claims 23-27 further comprising a bioactive agent.

29. (Original) The implantable device of claim 28 wherein the bioactive agent is selected from the group consisting of Everolimus, paclitaxel, docetaxel, estradiol, steroidal anti-inflammatory agents, antibiotics, anticancer agents, nitric oxide donors, super oxide dismutases, super oxide dismutases mimics, 4-amino-2,2,6,6-tetramethylpiperidine-1-oxyl (4-amino-TEMPO), ABT-578, tacrolimus, pimecrolimus, batimastat, mycophenolic acid, clobetasol, dexamethasone, rapamycin, 40-*O*-(3-hydroxy)propyl-rapamycin, 40-*O*-[2-(2-hydroxy)ethoxy]ethyl-rapamycin, or 40-*O*-tetrazole-rapamycin, antiproliferative agents, non-steroidal anti-inflammatory agents, immunosuppressive agents, antimigratory agents, and a combination thereof.

30. (Currently amended) An implantable device comprising a coating which comprises a poly(ester amide) (PEA) and at least one low surface energy polymer additive, wherein the at least one low surface energy polymer additive comprises a PEA miscible block or PEA miscible backbone.

31. (Original) The implantable device of claim 30 wherein the at least one low surface energy polymer additive is selected from the group consisting of Teflon (poly(tetrafluoroethylene), FEP (fluorinated ethylene-propylene), poly(tetrafluoroethylene-co-hexafluoropropene), PVDF (polyvinylidene fluoride), poly(fluoroalkenes), polysilanes, polysiloxanes, silicone (polydimethylsiloxane), hydrocarbon polymers, polyethylene, polypropylene, polystyrene, polybutadiene and combinations thereof.

32. (Original) The implantable device of claims 30 or 31 further comprising a bioactive agent.

33. (Original) The implantable device of claim 32 wherein the bioactive agent is selected from the group consisting of Everolimus, paclitaxel, docetaxel, estradiol, steroidal anti-inflammatory agents, antibiotics, anticancer agents, nitric oxide donors, super oxide dismutases, super oxide dismutases mimics, 4-amino-2,2,6,6-tetramethylpiperidine-1-oxyl (4-amino-TEMPO), ABT-578, tacrolimus, pimecrolimus, batimastat, mycophenolic acid, clobetasol, dexamethasone, rapamycin, 40-*O*-(3-hydroxy)propyl-rapamycin, 40-*O*-[2-(2-hydroxy)ethoxy]ethyl-rapamycin, or 40-*O*-tetrazole-rapamycin, antiproliferative agents, non-steroidal anti-inflammatory agents, immunosuppressive agents, antimigratory agents, and a combination thereof.

34. (Original) The implantable device of claim 23 which is a stent.

35. (Original) The implantable device of claim 24 which is a stent.

36. (Original) The implantable device of claim 25 which is a stent.

37. (Original) The implantable device of claim 26 which is a stent.

38. (Original) The implantable device of claim 27 which is a stent.

39. (Original) The implantable device of claim 30 which is a stent.

40. (Original) The implantable device of claim 31 which is a stent.

41. (Original) The implantable device of claim 28 which is a drug-eluting stent.

42. (Original) The implantable device of claim 29 which is a drug-eluting stent.

43. (Original) The implantable device of claim 32 which is a drug-eluting stent.

44. (Original) The implantable device of claim 33 which is a drug-eluting stent.

45. (Original) A method of treating a disorder in a human being by implanting in the human being a stent as defined in claim 34,

wherein the disorder is selected from the group consisting of atherosclerosis, thrombosis, restenosis, hemorrhage, vascular dissection or perforation, vascular aneurysm, vulnerable plaque, chronic total occlusion, claudication, anastomotic proliferation for vein and artificial grafts, bile duct obstruction, ureter obstruction, tumor obstruction, and combinations thereof.

46. (Original) A method of treating a disorder in a human being by implanting in the human being a stent as defined in claim 35,

wherein the disorder is selected from the group consisting of atherosclerosis, thrombosis, restenosis, hemorrhage, vascular dissection or perforation, vascular aneurysm, vulnerable plaque, chronic total occlusion, claudication, anastomotic proliferation for vein and artificial grafts, bile duct obstruction, ureter obstruction, tumor obstruction, and combinations thereof.

47. (Original) A method of treating a disorder in a human being by implanting in the human being a stent as defined in claim 36,

wherein the disorder is selected from the group consisting of atherosclerosis, thrombosis, restenosis, hemorrhage, vascular dissection or perforation, vascular aneurysm, vulnerable plaque, chronic total occlusion, claudication, anastomotic proliferation for vein and artificial grafts, bile duct obstruction, ureter obstruction, tumor obstruction, and combinations thereof.

48. (Original) A method of treating a disorder in a human being by implanting in the human being a stent as defined in claim 37,

wherein the disorder is selected from the group consisting of atherosclerosis, thrombosis, restenosis, hemorrhage, vascular dissection or perforation, vascular aneurysm, vulnerable plaque, chronic total occlusion, claudication, anastomotic proliferation for vein and artificial grafts, bile duct obstruction, ureter obstruction, tumor obstruction, and combinations thereof.

49. (Original) A method of treating a disorder in a human being by implanting in the human being a stent as defined in claim 38,

wherein the disorder is selected from the group consisting of atherosclerosis, thrombosis, restenosis, hemorrhage, vascular dissection or perforation, vascular aneurysm, vulnerable plaque, chronic total occlusion, claudication, anastomotic proliferation for vein and artificial grafts, bile duct obstruction, ureter obstruction, tumor obstruction, and combinations thereof.

50. (Original) A method of treating a disorder in a human being by implanting in the human being a stent as defined in claim 39,

wherein the disorder is selected from the group consisting of atherosclerosis, thrombosis, restenosis, hemorrhage, vascular dissection or perforation, vascular aneurysm, vulnerable plaque, chronic total occlusion, claudication, anastomotic proliferation for vein and artificial grafts, bile duct obstruction, ureter obstruction, tumor obstruction, and combinations thereof.

51. (Original) A method of treating a disorder in a human being by implanting in the human being a stent as defined in claim 42,

wherein the disorder is selected from the group consisting of atherosclerosis, thrombosis, restenosis, hemorrhage, vascular dissection or perforation, vascular aneurysm, vulnerable plaque, chronic total occlusion, claudication, anastomotic proliferation for vein and artificial grafts, bile duct obstruction, ureter obstruction, tumor obstruction, and combinations thereof.

52. (Original) A method of treating a disorder in a human being by implanting in the human being a stent as defined in claim 44,

wherein the disorder is selected from the group consisting of atherosclerosis, thrombosis, restenosis, hemorrhage, vascular dissection or perforation, vascular aneurysm, vulnerable plaque, chronic total occlusion, claudication, anastomotic proliferation for vein and artificial grafts, bile duct obstruction, ureter obstruction, tumor obstruction, and combinations thereof.

53. (Previously presented) The method of claim 1, wherein the coating is biologically benign.

54. (Previously presented) The method of claim 8, wherein the coating is biologically benign.

55. (Previously presented) The coating of claim 12, which is biologically benign.

56. (Previously presented) The coating of claim 19, which is biologically benign.

57. (Previously presented) The implantable device of claim 23, wherein the coating is biologically benign.

58. (Previously presented) The implantable device of claim 30, wherein the coating is biologically benign.

Remarks

Claims 1-58 are pending. Claims 1-58 are rejected.

Information Disclosure Statement

Applicants filed Information Disclosure Statements (IDSs) on May 6, 2004, July 28, 2005, November 2, 2006 and December 27, 2006, respectively. However, **the IDSs filed on May 6, 2004, and December 27, 2006 have not been returned to the Applicants. Applicants respectfully request the Examiner to sign off and return to Applicants these IDSs**.

In the returned IDS filed on November 2, 2006, **the Examiner did not initial references A58-A68 and B1-B5. Applicants respectfully request the Examiner to initial these references and return to us again the IDS filed on November 2, 2006.**

Rejections under 35 U.S.C. § 103

Claims 1-58 are rejected under 35 U.S.C. §103(a) as being obvious over WO 03/022323 A1 by Pacetti et al. ("Pacetti") in view of WO 98/32398 A1 by Roby et al. ("Roby").

Claim 1 defines a method for forming a poly(ester amide) (PEA) coating with enhanced mechanical and release rate properties. The method includes (a) applying to an implantable device a solution or suspension of a composition comprising **PEA and a low surface energy, surface blooming polymer**, and (b) forming a coating on the implantable device comprising PEA and the low surface energy, surface blooming polymer. **The low surface energy, surface blooming polymer includes a PEA miscible block or PEA miscible backbone**.

Pacetti describes a coating for reducing the release rate of a therapeutic agent from the coating. The coating includes a polymer capable of maintaining its crystalline lattice structure while the therapeutic agent is released from the coating. As the Examiner correctly notes, Pacetti does not describe a coating that includes a PEA.

The Examiner alleges that a crystalline polymer is a low surface energy polymer. Applicants respectfully submit that the question of whether a polymer is a crystalline polymer so as to make it a low surface energy polymer misses the point. **The low surface energy, surface blooming polymer as defined in claim 1 is defined to include a PEA miscible block or PEA miscible backbone. This attribute is clearly missing in Pacetti.**

Roby describes the preparation of a poly(ester amide) (PEA) polymer that can be used for fabrication of surgical devices. However, **there is no teaching or description in Roby of a coating comprising a composition that comprises a PEA polymer and a low surface energy, surface blooming polymer that includes a PEA miscible block or PEA miscible backbone**. Pacetti and Roby, individually or combined, fail to describe or teach these elements. Therefore, claim 1 is patentably allowable over Pacetti and Roby, individually or combined, under 35 U.S.C. 103(a). Claims 2-7 and 53 depend from claim 1 and are patentable over Pacetti and Roby, individually or combined, under 35 U.S.C. 103(a)for at least the same reason.

Claim 8 defines a method of forming a coating having **a PEA polymer and at least one low surface energy polymer additive. The at least one low surface energy polymer additive comprises a PEA miscible block or PEA miscible backbone**. As discussed above, Pacetti and Roby, individually or combined, fail to describe or teach these elements. Therefore, claim 8 is patentably allowable over Pacetti and Roby, individually or combined, under 35 U.S.C. 103(a). Claims 9-11 and 54 depend from claim 8 and are patentable over Pacetti and Roby, individually or combined, under 35 U.S.C. 103(a) for at least the same reason.

Claim 12 defines coating composition for coating an implantable device. The composition comprises **a poly(ester amide) (PEA) and a low surface energy, surface blooming polymer. The low surface energy, surface blooming polymer comprises a PEA**

miscible block or PEA miscible backbone. As discussed above, Pacetti and Roby, individually or combined, fail to describe or teach these elements. Therefore, claim 12 is patentably allowable over Pacetti and Roby, individually or combined, under 35 U.S.C. 103(a). Claims 13-18 and 55 depend from claim 12 and are patentable over Pacetti and Roby, individually or combined, under 35 U.S.C. 103(a) for at least the same reason.

Claim 19 defines a coating having **a PEA polymer and at least one low surface energy polymer additive. The at least one low surface energy polymer additive comprises a PEA miscible block or PEA miscible backbone**. As the discussion of claim 8 shows, Pacetti and Roby, individually or combined, fail to describe or teach these elements. Therefore, claim 19 is patentably allowable over Pacetti and Roby, individually or combined, under 35 U.S.C. 103(a). Claims 20-22 and 56 depend from claim 19 and are patentable over Pacetti and Roby, individually or combined, under 35 U.S.C. 103(a) for at least the same reason.

Claim 23 defines a medical device comprising a coating which comprises **a poly(ester amide) (PEA) and a low surface energy, surface blooming polymer. The low surface energy, surface blooming polymer comprises a PEA miscible block or PEA miscible backbone**. As discussed above, Pacetti and Roby, individually or combined, fail to describe or teach these elements. Therefore, claim 23 is patentably allowable over Pacetti and Roby, individually or combined, under 35 U.S.C. 103(a). Claims 24-29, 34-38, 41, 42, 45-49, 51 and 57 depend from claim 23 and are patentable over Pacetti and Roby, individually or combined, under 35 U.S.C. 103(a) for at least the same reason.

Claim 30 defines a medical device comprising a coating having **a PEA polymer and at least one low surface energy polymer additive. The at least one low surface energy polymer additive comprises a PEA miscible block or PEA miscible backbone**. As discussed above,

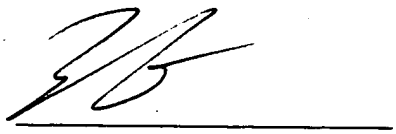
Pacetti and Roby, individually or combined, fail to describe or teach these elements. Therefore, claim 30 is patentably allowable over Pacetti and Roby, individually or combined, under 35 U.S.C. 103(a). Claims 31-33, 39, 40, 43, 44, 50, 52 and 58 depend from claim 30 and are patentable over Pacetti and Roby, individually or combined, under 35 U.S.C. 103(a) for at least the same reason.

The undersigned authorizes the examiner to charge any fees that may be required or credit of any overpayment to be made to Deposit Account No. 07-1850.

Withdrawal of the rejection and allowance of the claims are respectfully requested. **If the Examiner has any suggestions or amendments to the claims to place the claims in condition for allowance, applicant would prefer a telephone call to the undersigned attorney for approval of an Examiner's amendment.** If the Examiner has any questions or concerns, the Examiner is invited to telephone the undersigned attorney at (415) 393-9885.

Date: March 22, 2007

Respectfully submitted,



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,139	06/03/2004	Jessica R. DesNoyer	50623.326	2159

7590 06/12/2007

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DOCKETED: NON-FINAL: 9/12/07

JUN 19 2007

BY: JJb Atty: ZL

SQUIRE, SANDERS & DEMPSEY

EXAMINER	
ROGERS, JAMES WILLIAM	
ART UNIT	**PAPER NUMBER**
1618	
MAIL DATE	**DELIVERY MODE**
06/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/750,139	DESNOYER ET AL.	
	Examiner	Art Unit	
	James W. Rogers, Ph.D.	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/29/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/22/2007 has been entered. The amendments to the claims filed 03/22/2007 have been entered.

Claim Objections

Claims 6-7,17-18,28-29 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend upon another multiply dependent claim. See MPEP § 608.01(n). To expedite the examining process the examiner treated claim 6 as though it depended only upon claim 5, claim 17 as though it depended only upon claim 16 and 28 as though it depended upon claim 27.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti (WO 03/022323 A1, cited by applicants in IDS filed 11/06/2006) and in view of Roby et al. (WO 98/32398 A1, cited by applicant in IDS filed 11/06/2006).

Pacetti discloses a coating for reducing the rate release of drugs from stents in which the stent includes a polymer capable of maintaining its crystalline lattice structure while the therapeutic agent is released from the stent. See abstract. The polymers include polyurethanes with a polydimethylsiloxane soft segments, poly(vinylidene fluoride-co-methacrylic acid), styrene-ethylene-styrene block copolymer, polytetrafluoroethylene ect. See [0020]-[0021] and claims 11,16-17. The therapeutic agents included anti proliferative-substances, antibiotics, paclitaxel ect. See [0028].

Regarding the limitation that the implantable device is applied to a solution of PEA and a low surface energy, surface blooming polymer, Pacetti discloses that the composition can be applied by any conventional method including spraying the composition on the device or by immersing the device in the composition. See [0023]. Regarding claims 45-52 Pacetti discloses several methods of using the coated stents including treatment of obstructions caused by tumors and for treating occluded regions of blood vessels caused by abnormal or inappropriate migration and proliferation of smooth muscle tissue cells, thrombosis and restenosis. See [0032].

Pacetti does not disclose the use of PEA in combination with the crystalline polymers (same as low surface energy polymer or low surface energy, surface blooming polymer), to produce a coating containing a therapeutic for a stent.

Roby discloses the preparation of polyesteramides and surgical devices fabricated from them. See abstract and pag 1 lin 1-21. Roby is used mostly for the disclosure within that polyesteramides can be used as a coating for surgical devices and the polyesteramide surgical devices could also incorporate therapeutic agents such as antimicrobial agents. See pag 6 lin 3-pag 8 lin 18. The polyesteramide compositions could also be blended with other absorbable or non-absorbable compositions. Roby disclosed that the advantages or significance of PEA for use in medical devices was the susceptibility of their ester linkages to hydrolyze, conferring upon PEA the ability to be absorbed or resorbed by the body and the amide linkages confer upon them desirable mechanical properties. Regarding claims 53-58 it is obvious that since both the coatings described in Pacetti and Roby are used for medical devices for use in the body the

coating would be biologically benign and since the combination of the coatings described in the references above are the same as applicants claimed invention it is also obvious that the coatings would have the same properties, including biological properties. Regarding applicants newly amended claims which enter the proviso that both the low surface energy, surface blooming polymer or polymer additive comprises a PEA miscible block or a PEA miscible backbone, since by combination the two references disclose the same type of polymers and the same type of polymer additives the claim limitation is obviously met because the same compounds will have the same miscibility properties. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case or either anticipation or obviousness has been established, Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

It would have been prime facie obvious to a person of ordinary skill in the art at the time the claimed invention was made to combine the art described in the documents above because Pacetti disclosed the use of both the same low surface energy polymers and low surface energy, surface blooming polymers for a stent coating containing a therapeutic as applicants claims while Roby disclosed that coatings for surgical devices containing PEA and therapeutics was already well known in the art at the time of the invention. The motivation to combine the above documents would be to produce and

use a coated stent in which the coating comprised a therapeutic, PEA and a highly crystalline hydrophobic polymer (same as applicants low surface energy polymer). The advantage of such a coating would be that the combination would provide a biologically absorbable coating with desirable mechanical properties from the PEA polymer disclosed in Roby and a controlled release of the therapeutic from the crystalline polymers disclosed in Pacetti. One of ordinary skill in the art would have a reasonable expectation of success in combining the PEA polymers of Roby with the polymers of Pacetti because both polymers are disclosed as useful in the same field of endeavor being polymers useful as coatings for a stent. Thus, the claimed invention, taken as a whole was *prima facie* obvious over the combined teachings of the prior art.

Response to Arguments

Applicant's arguments filed 03/22/2007 have been fully considered but they are not persuasive.

Applicants asserts that neither Pacetti or Roby disclose a low surface energy surface blooming polymer or polymer additive that includes a miscible PEA block or backbone.

The relevance of this assertion is unclear. Since by combination the two references disclose the same type of polymers and the same type of polymer additives the claim limitation is obviously met because the same compounds will have the same miscibility properties. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case or either anticipation or

obviousness has been established, Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER

FORM PTO-1449 (Modified) US DEPARTMENT OF COMMERCE
US Patent and Trademark Office

INFORMATION DISCLOSURE CITATION in an Application

(Use several sheets if necessary)

Docket No.	Application No.
50623.326	10/750,139
Applicant	
DesNoyer et al.	
Filing Date	**Group Art Unit**
June 3, 2004	1755

U.S. PATENT DOCUMENTS

Examiner Initial	Ref. No.	Document Number	Date of Patent	Name	Class	Subclass	Filing Date if Appropriate
	A1	2,072,303	3/2/37	Herrmann et al.			
	A2	4,304,767	12/8/81	Heller et al.			
	A3	4,931,287	6/5/90	Bae et al.			
	A4	5,019,096	5/28/91	Fox, Jr. et al.			
	A5	5,163,952	11/17/92	Froix			
	A6	5,258,020	11/2/93	Froix			
	A7	RE 4,733,665	1/11/94	Palmaz			
	A8	5,581,387	12/3/96	Cahill			
	A9	5,584,877	12/17/96	Miyake et al.			
	A10	5,607,467	3/4/97	Froix			
	A11	5,616,338	4/1/97	Fox, Jr. et al.			
	A12	5,674,242	10/7/97	Phan et al.			
	A13	5,723,219	3/3/98	Kolluri et al.			
	A14	5,759,205	6/2/98	Valentini			
	A15	5,861,387	1/19/99	Labrie et al.			
	A16	5,879,713	3/9/99	Roth et al.			
	A17	5,932,299	8/3/99	Katoot			
	A18	5,962,138	10/5/99	Kolluri et al.			
	A19	6,143,354	11/7/00	Koulik et al.			
	A20	6,159,978	12/12/00	Myers et al.			
	A21	6,177,523	1/23/01	Reich et al.			
	A22	6,180,632	1/30/01	Myers et al.			
	A23	6,214,901	4/10/01	Chudzik et al.			
	A24	6,245,760	6/12/01	He et al.			
	A25	6,248,129	6/19/01	Froix			
	A26	6,258,371	7/10/01	Koulik et al.			
	A27	6,262,034	7/17/01	Mathiowitz et al.			

	A28	6,270,788	8/7/01	Koulik et al.			
	A29	6,277,449	8/21/01	Kolluri et al.			
	A30	6,344,035	2/5/02	Chudzik et al.			
	A31	6,387,379	5/14/02	Goldberg et al.			
	A32	6,482,834	11/19/02	Spada et al.			
	A33	6,503,538	1/7/03	Chu et al.			
	A34	6,524,347	2/25/03	Myers et al.			
	A35	6,528,526	3/4/03	Myers et al.			
	A36	6,530,950	3/11/03	Alvarado et al.			
	A37	6,530,951	3/11/03	Bates et al.			
	A38	6,585,765	7/1/03	Hossainy et al.			
	A39	6,616,765	9/9/03	Hossaony et al.			
	A40	6,623,448	9/23/03	Slater			
	A41	6,625,486	9/23/03	Lundkvist et al.			
	A42	6,645,135	11/11/03	Bhat			
	A43	6,645,195	11/11/03	Bhat et al.			
	A44	6,656,216	12/2/03	Hossainy et al.			
	A45	6,656,506	12/2/03	Wu et al.			
	A46	6,660,034	12/9/03	Mandrusov et al.			
	A47	6,663,662	12/16/03	Pacetti et al.			
	A48	6,663,880	12/16/03	Roorda et al.			
	A49	6,666,880	12/23/03	Chiu et al.			
	A50	6,673,154	1/6/04	Pacetti et al.			
	A51	6,673,385	1/6/04	Ding et al.			
	A52	6,689,099	2/10/04	Mirzaee			
	A53	6,695,920	2/24/04	Pacetti et al.			
	A54	6,703,040	3/9/04	Katsarava et al.			
	A55	6,706,013	3/16/04	Bhat et al.			
	A56	6,709,514	3/23/04	Hossainy			
	A57	6,712,845	3/30/04	Hossainy			

9/1	A58	6,713,119	3/30/04	Hossainy et al.			
	A59	6,716,444	4/6/04	Castro et al.			
	A60	6,723,120	4/20/04	Yan			
	A61	6,733,768	5/11/04	Hossainy et al.			
	A62	6,740,040	5/25/04	Mandrusov et al.			
	A63	6,743,462	6/1/04	Pacetti			
	A64	6,749,626	6/15/04	Bhat et al.			
	A65	6,753,071	6/22/04	Pacetti et al.			
	A66	6,758,859	7/6/04	Dang et al.			
	A67	6,759,054	7/6/04	Chen et al.			
	A68	6,764,505	7/20/04	Hossainy et al.			
	A69	10/630,250		Pacetti et al.			7/30/02
	A70	10/718,278		Hossainy et al.			11/19/03
	A71	10/719,516		Tang et al.			11/21/03
	A72	10/738,704		Pacetti et al.			12/16/03
	A73	10/741,214		Pacetti et al.			12/19/03
	A74	10/805,036		Pacetti			3/16/04
	A75	10/816,072		Dugan et al.			3/31/04
	A76	10/835,656		Tang et al.			4/30/04
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	C3	Moreno et al., *Macrophage Infiltration Predicts Restenosis After Coronary Intervention in Patients with Unstable Angina*, Circulation, vol. 94, no. 12, (1996) pp. 3098-3102.
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EXAMINER AR	DATE CONSIDERED 5/21/2007

EXAMINER: Initial if references considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 (Modified) US Patent and Trademark Office	US DEPARTMENT OF COMMERCE	Docket No. 50623.326	Application No. 10/750,139
INFORMATION DISCLOSURE CITATION in an Application (Use several sheets if necessary)		Applicant: Jessica R. DesNoyer et al	
		Filing Date: June 3, 2004	Group Art Unit: 1618

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QA	A1	6,500,481	12/31/02	Vanderlaan et al.			
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Examiner Initial	Ref. No.	Document Number	Date of Publication	Country	Class	Subclass	Abstract Translation Yes	Abstract Translation No
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EXAMINER	DATE CONSIDERED
	5/21/2007

EXAMINER: Initial if references considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Electronic Acknowledgement Receipt

EFS ID:	2189247
Application Number:	10750139
International Application Number:	
Confirmation Number:	2159
Title of Invention:	Poly(ester amide) coating composition for implantable devices
First Named Inventor/Applicant Name:	Jessica R. DesNoyer
Correspondence Address:	Squire, Sanders & Dempsey, L.L.P. - Suite 300 1 Maritime Plaza San Francisco CA 94111 US 4159540200 -
Filer:	Ram W. Sabnis
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Attorney Docket Number:	50623.326
Receipt Date:	12-SEP-2007
Filing Date:	03-JUN-2004
Time Stamp:	17:46:47
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)
1	Amendment - After Non-Final Rejection	50623_326Resp.PDF	599294 083678f917e4f1e38c77569298502880a42a753	no	19

Warnings:	
Information:	
Total Files Size (in bytes):	599294

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	DesNoyer et al.	Examiner:	James William Rogers
Serial No.:	10/750,139	Art Unit:	1618
Filed:	June 3, 2004		

Title: Poly(Ester Amide) Coating Composition For Implantable Devices

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

RESPONSE TO OFFICE ACTION

Dear Examiner Rogers:

This communication responds to the Office Action mailed on June 12, 2007.

In the claims

1. (Previously presented) A method for forming a poly(ester amide) (PEA) coating with enhanced mechanical and release rate properties, comprising:

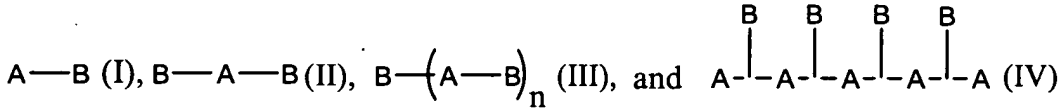
applying to an implantable device a solution or suspension of a composition comprising a PEA and a low surface energy, surface blooming polymer, and

forming a coating on the implantable device comprising PEA and the low surface energy, surface blooming polymer,

wherein the low surface energy, surface blooming polymer comprises a PEA miscible block or PEA miscible backbone.

2. (Previously presented) The method of claim 1 wherein the low surface energy, surface blooming polymer is selected from the group consisting of a block copolymer comprising a block miscible with the PEA and a hydrophobic block, a polymer comprising a backbone miscible with PEA and hydrophobic pendant groups, and a combination thereof.

3. (Original) The method of claim 1 wherein the low surface energy polymer is selected from the group consisting of formulae I-IV of the following structure:



wherein A is a PEA miscible block or PEA miscible backbone, and

wherein B is selected from the group consisting of a surface blooming block and a surface blooming pendant group.

4. (Currently amended) The method of claim 3 wherein A is selected from the group consisting of ~~polyurethane~~, poly(ester-urea) urethane, polyglycol, poly(tetramethylene glycol), poly(propylene glycol), polycaprolactone, ethylene vinyl alcohol copolymer, poly(butyl

methacrylate), poly(methacrylate), poly(acrylate), poly(ether-urethane), poly(ester-urethane), poly(carbonate-urethane), poly(silicone-urethane), poly(urea-urethane), poly(glycolide), poly(L-latide), poly(l-lactide-co-glycolide), poly(D,L-lactide), poly(D,L-lactide-co-glycolide), poly(D,L-lactide-co-L-lactide), poly(glycolide-co-caprolactone), poly(D,L-lactide-co-caprolactone), poly(L-lactide-co-caprolactone), poly(dioxanone), poly(trimethylene carbonate), poly(trimethylene carbonate) copolymers, poly(3-hydroxybutyrate), poly(3-hydroxyvalerate), poly(4-hydroxybutyrate), poly(3-hydroxybutyrate-co-3-hydroxyvalerate), ~~styrene-butadiene-styrene block copolymer, styrene-butylene/ethylene-styrene block copolymer~~, styrene-isobutylene-styrene triblock copolymer, poly(ethylene-co-vinyl acetate), and a combination thereof; and

wherein B is selected from the group consisting of a linear or branched alkyl chain, polysilanes, polysiloxanes, poly(dimethylsiloxane), a linear or branched perfluoro chain, and a combination thereof.

5. (Original) The method of claim 1 wherein the low surface energy polymer is selected from the group consisting of organosilicone surfactants, block copolymers of alkyl chains with polyglycol chains, fluoro surfactants, block copolymers of polydimethylsiloxane and polycaprolactone, polyurethanes end-capped with long chain perfluoro alcohols, poly(ester-urea)urethanes end-capped with long chain perfluoroalcohols, polyurethanes end-capped with alkyl chains, polyurethanes end-capped with polydimethylsiloxane, copolymers of polycaprolactone and fluoroalcohols, and combinations thereof.

6. (Original) The method of any of claims 1-5 wherein the composition further comprises a bioactive agent.

7. (Original) The method of claim 6 wherein the bioactive agent is selected from the group consisting of Everolimus, paclitaxel, docetaxel, estradiol, steroidal anti-inflammatory agents, antibiotics, anticancer agents, nitric oxide donors, super oxide dismutases, super oxide dismutases mimics, 4-amino-2,2,6,6-tetramethylpiperidine-1-oxyl (4-amino-TEMPO), ABT-578, tacrolimus, pimecrolimus, batimastat, mycophenolic acid, clobetasol, dexamethasone, rapamycin, 40-*O*-(3-hydroxy)propyl-rapamycin, 40-*O*-[2-(2-hydroxy)ethoxy]ethyl-rapamycin, or 40-*O*-tetrazole-rapamycin, antiproliferative agents, non-steroidal anti-inflammatory agents, immunosuppressive agents, antimigratory agents, and a combination thereof.

8. (Previously presented) A method for forming a poly(ester amide) (PEA) coating with enhanced mechanical and release rate properties, comprising:

applying to an implantable device a solution or suspension of a composition comprising a PEA and at least one low surface energy polymer additive, and

forming a coating on the implantable device comprising PEA and the at least one low surface energy polymer additive,

wherein the at least one low surface energy polymer additive comprises a PEA miscible block or PEA miscible backbone.

9. (Original) The method of claim 8 wherein the at least one low surface energy polymer additive is selected from the group consisting of Teflon (poly(tetrafluoroethylene), FEP (fluorinated ethylene-propylene), poly(tetrafluoroethylene-co-hexafluoropropene), PVDF (polyvinylidene fluoride), poly(fluoroalkenes), polysilanes, polysiloxanes, silicone (polydimethylsiloxane), hydrocarbon polymers, polyethylene, polypropylene, polystyrene, polybutadiene and combinations thereof.

10. (Original) The method of claims 8 or 9 wherein the composition further comprises a bioactive agent.

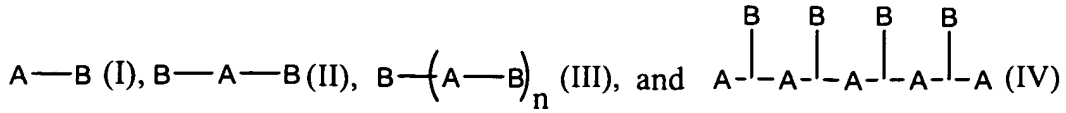
11. (Original) The method of claim 10 wherein the bioactive agent is selected from the group consisting of Everolimus, paclitaxel, docetaxel, estradiol, steroidal anti-inflammatory agents, antibiotics, anticancer agents, nitric oxide donors, super oxide dismutases, super oxide dismutases mimics, 4-amino-2,2,6,6-tetramethylpiperidine-1-oxyl (4-amino-TEMPO), ABT-578, tacrolimus, pimecrolimus, batimastat, mycophenolic acid, clobetasol, dexamethasone, rapamycin, 40-*O*-(3-hydroxy)propyl-rapamycin, 40-*O*-[2-(2-hydroxy)ethoxy]ethyl-rapamycin, or 40-*O*-tetrazole-rapamycin, antiproliferative agents, non-steroidal anti-inflammatory agents, immunosuppressive agents, antimigratory agents, and a combination thereof.

12. (Previously presented) A coating composition for coating an implantable device comprising a poly(ester amide) (PEA) and a low surface energy, surface blooming polymer,

wherein the low surface energy, surface blooming polymer comprises a PEA miscible block or PEA miscible backbone.

13. (Previously presented) The composition of claim 13 wherein the low surface energy, surface blooming polymer is selected from the group consisting of a block copolymer comprising a block miscible with the PEA and a hydrophobic block, a polymer comprising a backbone miscible with PEA and hydrophobic pendant groups, and a combination thereof.

14. (Original) The composition of claim 12 wherein the low surface energy, surface blooming polymer is selected from the group consisting of formulae I-IV of the following structure:



wherein A is a PEA miscible block or PEA miscible backbone, and

wherein B is selected from the group consisting of a surface blooming block and a surface blooming pendant group.

15. (Original) The composition of claim 14 wherein A is selected from the group consisting of polyurethane, poly(ester-urea) urethane, polyglycol, poly(tetramethylene glycol), poly(propylene glycol), polycaprolactone, ethylene vinyl alcohol copolymer, poly(butyl methacrylate), poly(methacrylate), poly(acrylate), and a combination thereof; and

wherein B is selected from the group consisting of a linear or branched alkyl chain, polysilanes, polysiloxanes, poly(dimethylsiloxane), a linear or branched perfluoro chain, and a combination thereof.

16. (Original) The composition of claim 15 wherein the low surface energy, surface blooming polymer is selected from the group consisting of organosilicone surfactants, block copolymers of alkyl chains with polyglycol chains, fluoro surfactants, block copolymers of polydimethylsiloxane and polycaprolactone, polyurethanes endcapped with long chain perfluoro alcohols, poly(ester-urea)urethanes endcapped with long chain perfluoro alcohols, polyurethanes endcapped with alkyl chains, polyurethanes endcapped with polydimethylsiloxane, and combinations thereof.

17. (Original) The composition of any of claims 12-16 further comprising a bioactive agent.

18. (Original) The composition of claim 17 wherein the bioactive agent is selected from the group consisting of Everolimus, paclitaxel, docetaxel, estradiol, steroidal anti-inflammatory agents, antibiotics, anticancer agents, nitric oxide donors, super oxide dismutases, super oxide dismutases mimics, 4-amino-2,2,6,6-tetramethylpiperidine-1-oxyl (4-amino-

TEMPO), ABT-578, tacrolimus, pimecrolimus, batimastat, mycophenolic acid, clobetasol, dexamethasone, rapamycin, 40-*O*-(3-hydroxy)propyl-rapamycin, 40-*O*-[2-(2-hydroxy)ethoxy]ethyl-rapamycin, or 40-*O*-tetrazole-rapamycin, antiproliferative agents, non-steroidal anti-inflammatory agents, immunosuppressive agents, antimigratory agents, and a combination thereof.

19. (Previously presented) A coating composition for coating an implantable device comprising a poly(ester amide) (PEA) and at least one low surface energy polymer additive, wherein the at least one low surface energy polymer additive comprises a PEA miscible block or PEA miscible backbone.

20. (Original) The composition of claim 19 wherein the at least one low surface energy polymer additive is selected from the group consisting of Teflon (poly(tetrafluoroethylene), FEP (fluorinated ethylene-propylene), poly(tetrafluoroethylene-co-hexafluoropropene), PVDF (polyvinylidene fluoride), poly(fluoroalkenes), polysilanes, polysiloxanes, silicone (polydimethylsiloxane), hydrocarbon polymers, polyethylene, polypropylene, polystyrene, polybutadiene and combinations thereof.

21. (Original) The composition of claims 19 or 20 further comprising a bioactive agent.

22. (Original) The composition of claim 21 wherein the bioactive agent is selected from the group consisting of Everolimus, paclitaxel, docetaxel, estradiol, steroidal anti-inflammatory agents, antibiotics, anticancer agents, nitric oxide donors, super oxide dismutases, super oxide dismutases mimics, 4-amino-2,2,6,6-tetramethylpiperidine-1-oxyl (4-amino-TEMPO), ABT-578, tacrolimus, pimecrolimus, batimastat, mycophenolic acid, clobetasol, dexamethasone, rapamycin, 40-*O*-(3-hydroxy)propyl-rapamycin, 40-*O*-[2-(2-

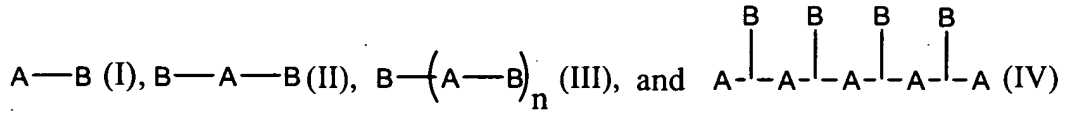
hydroxy)ethoxy]ethyl-rapamycin, or 40-*O*-tetrazole-rapamycin, antiproliferative agents, non-steroidal anti-inflammatory agents, immunosuppressive agents, antimigratory agents, and a combination thereof.

23. (Previously presented) An implantable device comprising a coating which comprises a poly(ester amide) (PEA) and a low surface energy, surface blooming polymer,

wherein the low surface energy, surface blooming polymer comprises a PEA miscible block or PEA miscible backbone.

24. (Previously presented) The implantable device of claim 23 wherein the low surface energy, surface blooming polymer is selected from the group consisting of a block copolymer comprising a block miscible with the PEA and a hydrophobic block, a polymer comprising a backbone miscible with PEA and hydrophobic pendant groups, and a combination thereof.

25. (Original) The implantable device of claim 24 wherein the low surface energy, surface blooming polymer is selected from the group consisting of formulae I-IV of the following structure:



wherein A is a PEA miscible block or PEA miscible backbone, and

wherein B is selected from the group consisting of a surface blooming block and a surface blooming pendant group.

26. (Original) The implantable device of claim 25 wherein A is selected from the group consisting of polyurethane, poly(ester-urea) urethane, polyglycol, poly(tetramethylene

glycol), poly(propylene glycol), polycaprolactone, ethylene vinyl alcohol copolymer, poly(butyl methacrylate), poly(methacrylate), poly(acrylate), and a combination thereof; and

wherein B is selected from the group consisting of a linear or branched alkyl chain, polysilanes, polysiloxanes, poly(dimethylsiloxane), a linear or branched perfluoro chain, and a combination thereof.

27. (Original) The implantable device of claim 26 wherein the low surface energy, surface blooming polymer is selected from the group consisting of organosilicone surfactants, block copolymers of alkyl chains with polyglycol chains, fluoro surfactants, block copolymers of polydimethylsiloxane and polycaprolactone, polyurethanes endcapped with long chain perfluoro alcohols, poly(ester-urea)urethanes endcapped with long chain perfluoro alcohols, polyurethanes endcapped with alkyl chains, polyurethanes endcapped with polydimethylsiloxane, and combinations thereof.

28. (Original) The implantable device of any of claims 23-27 further comprising a bioactive agent.

29. (Original) The implantable device of claim 28 wherein the bioactive agent is selected from the group consisting of Everolimus, paclitaxel, docetaxel, estradiol, steroidal anti-inflammatory agents, antibiotics, anticancer agents, nitric oxide donors, super oxide dismutases, super oxide dismutases mimics, 4-amino-2,2,6,6-tetramethylpiperidine-1-oxyl (4-amino-TEMPO), ABT-578, tacrolimus, pimecrolimus, batimastat, mycophenolic acid, clobetasol, dexamethasone, rapamycin, 40-*O*-(3-hydroxy)propyl-rapamycin, 40-*O*-[2-(2-hydroxy)ethoxy]ethyl-rapamycin, or 40-*O*-tetrazole-rapamycin, antiproliferative agents, non-steroidal anti-inflammatory agents, immunosuppressive agents, antimigratory agents, and a combination thereof.

30. (Previously presented) An implantable device comprising a coating which comprises a poly(ester amide) (PEA) and at least one low surface energy polymer additive, wherein the at least one low surface energy polymer additive comprises a PEA miscible block or PEA miscible backbone.

31. (Original) The implantable device of claim 30 wherein the at least one low surface energy polymer additive is selected from the group consisting of Teflon (poly(tetrafluoroethylene), FEP (fluorinated ethylene-propylene), poly(tetrafluoroethylene-co-hexafluoropropene), PVDF (polyvinylidene fluoride), poly(fluoroalkenes), polysilanes, polysiloxanes, silicone (polydimethylsiloxane), hydrocarbon polymers, polyethylene, polypropylene, polystyrene, polybutadiene and combinations thereof.

32. (Original) The implantable device of claims 30 or 31 further comprising a bioactive agent.

33. (Original) The implantable device of claim 32 wherein the bioactive agent is selected from the group consisting of Everolimus, paclitaxel, docetaxel, estradiol, steroidal anti-inflammatory agents, antibiotics, anticancer agents, nitric oxide donors, super oxide dismutases, super oxide dismutases mimics, 4-amino-2,2,6,6-tetramethylpiperidine-1-oxyl (4-amino-TEMPO), ABT-578, tacrolimus, pimecrolimus, batimastat, mycophenolic acid, clobetasol, dexamethasone, rapamycin, 40-*O*-(3-hydroxy)propyl-rapamycin, 40-*O*-[2-(2-hydroxy)ethoxy]ethyl-rapamycin, or 40-*O*-tetrazole-rapamycin, antiproliferative agents, non-steroidal anti-inflammatory agents, immunosuppressive agents, antimigratory agents, and a combination thereof.

34. (Original) The implantable device of claim 23 which is a stent.

35. (Original) The implantable device of claim 24 which is a stent.

36. (Original) The implantable device of claim 25 which is a stent.

37. (Original) The implantable device of claim 26 which is a stent.

38. (Original) The implantable device of claim 27 which is a stent.

39. (Original) The implantable device of claim 30 which is a stent.

40. (Original) The implantable device of claim 31 which is a stent.

41. (Original) The implantable device of claim 28 which is a drug-eluting stent.

42. (Original) The implantable device of claim 29 which is a drug-eluting stent.

43. (Original) The implantable device of claim 32 which is a drug-eluting stent.

44. (Original) The implantable device of claim 33 which is a drug-eluting stent.

45. (Original) A method of treating a disorder in a human being by implanting in the human being a stent as defined in claim 34,

wherein the disorder is selected from the group consisting of atherosclerosis, thrombosis, restenosis, hemorrhage, vascular dissection or perforation, vascular aneurysm, vulnerable plaque, chronic total occlusion, claudication, anastomotic proliferation for vein and artificial grafts, bile duct obstruction, ureter obstruction, tumor obstruction, and combinations thereof.

46. (Original) A method of treating a disorder in a human being by implanting in the human being a stent as defined in claim 35,

wherein the disorder is selected from the group consisting of atherosclerosis, thrombosis, restenosis, hemorrhage, vascular dissection or perforation, vascular aneurysm, vulnerable plaque, chronic total occlusion, claudication, anastomotic proliferation for vein and artificial grafts, bile duct obstruction, ureter obstruction, tumor obstruction, and combinations thereof.

47. (Original) A method of treating a disorder in a human being by implanting in the human being a stent as defined in claim 36,

wherein the disorder is selected from the group consisting of atherosclerosis, thrombosis, restenosis, hemorrhage, vascular dissection or perforation, vascular aneurysm, vulnerable plaque, chronic total occlusion, claudication, anastomotic proliferation for vein and artificial grafts, bile duct obstruction, ureter obstruction, tumor obstruction, and combinations thereof.

48. (Original) A method of treating a disorder in a human being by implanting in the human being a stent as defined in claim 37,

wherein the disorder is selected from the group consisting of atherosclerosis, thrombosis, restenosis, hemorrhage, vascular dissection or perforation, vascular aneurysm, vulnerable plaque, chronic total occlusion, claudication, anastomotic proliferation for vein and artificial grafts, bile duct obstruction, ureter obstruction, tumor obstruction, and combinations thereof.

49. (Original) A method of treating a disorder in a human being by implanting in the human being a stent as defined in claim 38,

wherein the disorder is selected from the group consisting of atherosclerosis, thrombosis, restenosis, hemorrhage, vascular dissection or perforation, vascular aneurysm, vulnerable plaque, chronic total occlusion, claudication, anastomotic proliferation for vein and artificial grafts, bile duct obstruction, ureter obstruction, tumor obstruction, and combinations thereof.

50. (Original) A method of treating a disorder in a human being by implanting in the human being a stent as defined in claim 39,

wherein the disorder is selected from the group consisting of atherosclerosis, thrombosis, restenosis, hemorrhage, vascular dissection or perforation, vascular aneurysm, vulnerable plaque, chronic total occlusion, claudication, anastomotic proliferation for vein and artificial grafts, bile duct obstruction, ureter obstruction, tumor obstruction, and combinations thereof.

51. (Original) A method of treating a disorder in a human being by implanting in the human being a stent as defined in claim 42,

wherein the disorder is selected from the group consisting of atherosclerosis, thrombosis, restenosis, hemorrhage, vascular dissection or perforation, vascular aneurysm, vulnerable plaque, chronic total occlusion, claudication, anastomotic proliferation for vein and artificial grafts, bile duct obstruction, ureter obstruction, tumor obstruction, and combinations thereof.

52. (Original) A method of treating a disorder in a human being by implanting in the human being a stent as defined in claim 44,

wherein the disorder is selected from the group consisting of atherosclerosis, thrombosis, restenosis, hemorrhage, vascular dissection or perforation, vascular aneurysm, vulnerable plaque, chronic total occlusion, claudication, anastomotic proliferation for vein and artificial grafts, bile duct obstruction, ureter obstruction, tumor obstruction, and combinations thereof.

53. (Previously presented) The method of claim 1, wherein the coating is biologically benign.

54. (Previously presented) The method of claim 8, wherein the coating is biologically benign.

55. (Previously presented) The coating of claim 12, which is biologically benign.

56. (Previously presented) The coating of claim 19, which is biologically benign.

57. (Previously presented) The implantable device of claim 23, wherein the coating is biologically benign.

58. (Previously presented) The implantable device of claim 30, wherein the coating is biologically benign.

Remarks

Claims 1-58 are pending. Claims 1-58 are rejected.

Objections to the Claims

The Examiner has objected the claims 6-7, 17-18, and 28-29 under 37 CFR 1.75(c) as allegedly being in improper form because a multiple dependent claim cannot depend upon another multiple dependent claim.

Claim 6 depends on any of claims 1-5 and is a proper multiple dependent claim (See MPEP § 608(n), I, A: Acceptable multiple dependent claim wording).

Claim 7 depends on claim 6 only and is a proper dependent claim (See MPEP § 608(i), 37 CFR 1.75(c)).

Claim 17 depends on any of claims 12-16 and is a proper multiple dependent claim (See MPEP § 608(n), I, A: Acceptable multiple dependent claim wording).

Claim 18 depends on claim 17 only and is a proper dependent claim (See MPEP § 608(i), 37 CFR 1.75(c)).

Claim 28 depends on any of claims 23-27 and is a proper multiple dependent claim (See MPEP § 608(n), I, A: Acceptable multiple dependent claim wording).

Claim 29 depends on claim 28 only and is a proper dependent claim (See MPEP § 608(i), 37 CFR 1.75(c)).

In sum, Applicants believe that these claims are in are proper form.

Rejections under 35 U.S.C. § 103(a)

Claims 1-58 are rejected under 35 U.S.C. §103(a) as being obvious over Pacetti (WO 03/022323) in view of Roby (WO 98/32398).

Claim 1 defines a method for forming a poly(ester amide) (PEA) coating with enhanced mechanical and release rate properties. The method includes (a) applying to an implantable device a solution or suspension of a composition comprising **PEA** and **a low surface energy, surface blooming polymer**, and (b) forming a coating on the implantable device comprising PEA and the low surface energy, surface blooming polymer. The low surface energy, surface blooming polymer **includes a PEA miscible block or PEA miscible backbone**. As described on Page 7, lines 10-22 of the instant application, the method will cause the surface of a coating thus formed to be enriched with the hydrophobic blooming component in the blooming polymer. This would reduce or prevent the interaction between the PEA polymer and the catheter balloon, thereby reducing potential mechanical failures of a PEA coating on an implantable device. Additionally, the hydrophobic, blooming component of the polymer would create a hydrophobic barrier at the coating surface, thereby retarding drug release from the PEA matrix. As a result, thinner coatings can be used to obtain the same release rate control of a thicker coating of PEA polymer without the surface blooming polymers. Further, the hydrophobic barrier would further reduce the interaction between water and the PEA matrix so as to reduce the degradation rate of the PEA polymer.

Pacetti describes a coating for reducing the release rate of a therapeutic agent from the coating. The coating includes a polymer capable of maintaining its crystalline lattice structure

while the therapeutic agent is released from the coating. As the Examiner correctly notes, Pacetti does not describe a coating that includes a PEA.

Further, Pacetti fails to teach or suggest a method of forming a coating for an implantable device using a composition comprises a low surface energy, surface blooming polymer that has **a PEA miscible block or a PEA miscible backbone as required by claim 1**.

Roby discloses the preparation of a poly(ester amide) (PEA) polymer that can be used for fabrication of surgical devices. However, **there is no teaching in Roby of a method of forming a coating** comprising applying to an implantable device a composition that comprises a PEA polymer and a low surface energy, surface blooming polymer that includes **a PEA miscible block or PEA miscible backbone**.

In sum, Pacetti and Roby, individually or combined, fail to teach or suggest these elements. Therefore, claim 1 is patentably allowable over Pacetti and Roby, individually or combined, under 35 U.S.C. 103(a). Claims 2-7 and 53 depend from claim 1 and are patentable over Pacetti and Roby, individually or combined, under 35 U.S.C. 103(a) for at least the same reason.

Claim 8 defines a method of forming a coating having a PEA polymer and at least one low surface energy polymer additive. The at least one low surface energy polymer additive comprises **a PEA miscible block or PEA miscible backbone**. As discussed above, Pacetti and Roby, individually or combined, fail to teach or suggest these elements. Therefore, claim 8 is patentably allowable over Pacetti and Roby, individually or combined, under 35 U.S.C. 103(a). Claims 9-11 and 54 depend from claim 8 and are patentable over Pacetti and Roby, individually or combined, under 35 U.S.C. 103(a) for at least the same reason.

Claim 12 defines coating composition for coating an implantable device. The composition comprises a poly(ester amide) (PEA) and a low surface energy, surface blooming polymer. The low surface energy, surface blooming polymer comprises **a PEA miscible block or PEA miscible backbone.** As discussed above, Pacetti and Roby, individually or combined, fail to teach or suggest these elements. Therefore, claim 12 is patentably allowable over Pacetti and Roby, individually or combined, under 35 U.S.C. 103(a). Claims 13-18 and 55 depend from claim 12 and are patentable over Pacetti and Roby, individually or combined, under 35 U.S.C. 103(a) for at least the same reason.

Claim 19 defines a coating having a PEA polymer and at least one low surface energy polymer additive. The at least one low surface energy polymer additive comprises **a PEA miscible block or PEA miscible backbone**. As the discussion of claim 8 shows, Pacetti and Roby, individually or combined, fail to teach or suggest these elements. Therefore, claim 19 is patentably allowable over Pacetti and Roby, individually or combined, under 35 U.S.C. 103(a). Claims 20-22 and 56 depend from claim 19 and are patentable over Pacetti and Roby, individually or combined, under 35 U.S.C. 103(a) for at least the same reason.

Claim 23 defines an implantable device comprising a coating which comprises a poly(ester amide) (PEA) and a low surface energy, surface blooming polymer. The low surface energy, surface blooming polymer comprises **a PEA miscible block or PEA miscible backbone**. As discussed above, Pacetti and Roby, individually or combined, fail to teach or suggest these elements. Therefore, claim 23 is patentably allowable over Pacetti and Roby, individually or combined, under 35 U.S.C. 103(a). Claims 24-29, 34-38, 41, 42, 45-49, 51 and

57 depend from claim 23 and are patentable over Pacetti and Roby, individually or combined, under 35 U.S.C. 103(a) for at least the same reason.

Claim 30 defines an implantable device comprising a coating having a PEA polymer and at least one low surface energy polymer additive. The at least one low surface energy polymer additive comprises **a PEA miscible block or PEA miscible backbone**. As discussed above, Pacetti and Roby, individually or combined, fail to teach or suggest these elements. Therefore, claim 30 is patentably allowable over Pacetti and Roby, individually or combined, under 35 U.S.C. 103(a). Claims 31-33, 39, 40, 43, 44, 50, 52 and 58 depend from claim 30 and are patentable over Pacetti and Roby, individually or combined, under 35 U.S.C. 103(a) for at least the same reason.

The undersigned authorizes the Examiner to charge any fees that may be required or credit of any overpayment to be made to Deposit Account No. 07-1850.

Withdrawal of the rejection and allowance of the claims are respectfully requested. If the Examiner has any questions or concerns, the Examiner is invited to telephone the undersigned attorney at (415) 954-0313.

Date: September 12, 2007

Respectfully submitted,

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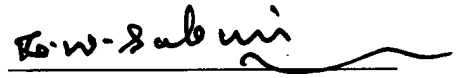

Ram W. Sabnis, Ph.D.
Patent Agent for Applicants
Reg. No. 58,868

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,139	06/03/2004	Jessica R. DesNoyer	50623.326	2159

7590 10/10/2007

Squire, Sanders & Dempsey, L.L.P.
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EXAMINER	
ROGERS, JAMES WILLIAM	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
10/10/2007	PAPER

FINAL OFFICE ACTION
RESPONSE DUE: 1/10/08
NTC of APPEAL DUE: 4/10/08

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DOCKETED: N/A

OCT 17 2007

BY: AV Atty: ZL/RS
SQUIRE, SANDERS & DEMPSEY

Office Action Summary	Application No.	Applicant(s)	
	10/750,139	DESNOYER ET AL.	
	Examiner	Art Unit	
	James W. Rogers, Ph.D.	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

The amendment to the claims filed 09/12/2007 has been entered. Applicants have amended claim 4. Any objection/rejection from the previous office action filed 04/30/2007 not addressed in the office action below has been withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Roby et al. (WO 98/32398 A1, cited previously) in view of Pinhcuck et al. (US 2002/0107330), this new rejection was necessitated by amendment.

Roby was disclosed previously in the office action dated 06/12/2007. Roby discloses PEA polymers useful in coating surgical devices. Roby does not disclose the low surface energy polymers as recited in claim 4.

Pinchuck discloses coatings over an intravascular or intervascular medical device comprising a biocompatible polymer that comprises an A block and a B block, the A-block includes polyolefin monomers that when polymerized will form an alkyl chain and a B-block that includes monomers of methacrylates. See abstract and [0027]-[0036]. Pinchuck also discloses that the medical devices can further comprise a copolymer that includes blocks of the following polymers polycaprolactone, polyglycolic acid, siloxane polymers and the like. See [0016]. Either of the copolymers described above would meet applicants claimed low surface energy polymer as recited in claim 4.

Thus the claimed invention would have been *prima facie* obvious since all the claimed elements such as PEA and the copolymers of claim 4 were known to be useful in coating medical devices and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Response to Arguments

Claims 1-3,5-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti (WO 03/022323 A1, cited by applicants in IDS filed 11/06/2006) and in view of Roby et al. (WO 98/32398 A1, cited by applicant in IDS filed 11/06/2006), for the reasons set forth in the office action dated 06/12/2007.

Applicant's arguments filed 09/12/2007 have been fully considered but they are not persuasive.

Applicants asserts that neither Pacetti or Roby disclose a low surface energy surface blooming polymer or polymer additive that includes a miscible PEA block or backbone nor do they teach or suggest a method of forming a coating for an implantable device using the above polymer combination.

The relevance of this assertion is unclear. Since by combination the two references disclose the same type of polymers and the same type of polymer additives the claim limitation is obviously met because the same compounds will have the same miscibility properties. Roby discloses PEA polymers in coating surgical devices while

Pacetti discloses polyurethanes with a polydimethylsiloxane soft segments useful in coating stents. From applicants own specification polyurethanes with a polydimethylsiloxane soft segment would meet a low surface energy surface blooming polymer or polymer additive that includes a miscible PEA block or backbone. See page 3 lin 15-page 4 lin 14 of applicants specification. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case or either anticipation or obviousness has been established, Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable.

Conclusion

No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP §706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system: Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER

Notice of References Cited	Application/Control No. 10/750,139	Applicant(s)/Patent Under Reexamination DESNOYER ET AL.	
	Examiner James W. Rogers, Ph.D.	Art Unit 1618	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-2002/0107330	08-2002	Pinchuk et al.	525/242
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

PTO/SB/31 (01-08)
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NOTICE OF APPEAL FROM THE EXAMINER TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

Docket Number (Optional): 50623.326

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on January 7, 2008

Signature: La Renda Meyer

Typed or printed name: La Renda Meyer (via PTO- EFS)

In re Application of: Jessica R. DesNoyer, et al.

Application Number	Filed
10/750,139	June 3, 2004

For: Poly(Ester Amide) Coating Composition for...

Art Unit	Examiner
1618	Rogers, James William

Applicant hereby **appeals** to the Board of Patent Appeals and Interferences from the last decision of the examiner.

The fee for this Notice of Appeal is (37 CFR 41.20(b)(1)) $ 510.00

☐ Applicant claims small entity status. See 37 CFR 1.27. Therefore, the fee shown above is reduced by half, and the resulting fee is: $ _____

☐ A check in the amount of the fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account. I have enclosed a duplicate copy of this sheet.

☑ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. 07-1850 . I have enclosed a duplicate copy of this sheet.

☐ A petition for an extension of time under 37 CFR 1.136(a) (PTO/SB/22) is enclosed.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)

☑ attorney or agent of record. Registration number 46,872

☐ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34. _____

/ZL/
Signature

Zhaoyang Li, Ph.D.
Typed or printed name

415-393-9885
Telephone number

January 7, 2008
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☑ *Total of 1 forms are submitted.

This collection of information is required by 37 CFR 41.31. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	DesNoyer et al.	Examiner:	James William Rogers
Serial No.:	10/750,139	Art Unit:	1618
Filed:	June 3, 2004	Confirmation No.	2159

Title: Poly(Ester Amide) Coating Composition For Implantable Devices

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Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

RESPONSE TO FINAL OFFICE ACTION

Dear Examiner Rogers:

This communication responds to the Final Office Action mailed on October 10, 2007.

In the claims

1. (Previously presented) A method for forming a poly(ester amide) (PEA) coating with enhanced mechanical and release rate properties, comprising:

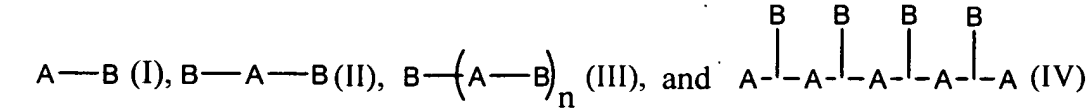
applying to an implantable device a solution or suspension of a composition comprising a PEA and a low surface energy, surface blooming polymer, and

forming a coating on the implantable device comprising PEA and the low surface energy, surface blooming polymer,

wherein the low surface energy, surface blooming polymer comprises a PEA miscible block or PEA miscible backbone.

2. (Previously presented) The method of claim 1 wherein the low surface energy, surface blooming polymer is selected from the group consisting of a block copolymer comprising a block miscible with the PEA and a hydrophobic block, a polymer comprising a backbone miscible with PEA and hydrophobic pendant groups, and a combination thereof.

3. (Original) The method of claim 1 wherein the low surface energy polymer is selected from the group consisting of formulae I-IV of the following structure:



wherein A is a PEA miscible block or PEA miscible backbone, and

wherein B is selected from the group consisting of a surface blooming block and a surface blooming pendant group.

4. (Previously presented) The method of claim 3 wherein A is selected from the group consisting of poly(ester-urea) urethane, polyglycol, poly(tetramethylene glycol), poly(propylene glycol), polycaprolactone, ethylene vinyl alcohol copolymer, poly(butyl

methacrylate), poly(methacrylate), poly(acrylate), poly(ether-urethane), poly(ester-urethane), poly(carbonate-urethane), poly(silicone-urethane), poly(urea-urethane), poly(glycolide), poly(L-latide), poly(l-lactide-co-glycolide), poly(D,L-lactide), poly(D,L-lactide-co-glycolide), poly(D,L-lactide-co-L-lactide), poly(glycolide-co-caprolactone), poly(D,L-lactide-co-caprolactone), poly(L-lactide-co-caprolactone), poly(dioxanone), poly(trimethylene carbonate), poly(trimethylene carbonate) copolymers, poly(3-hydroxybutyrate), poly(3-hydroxyvalerate), poly(4-hydroxybutyrate), poly(3-hydroxybutyrate-co-3-hydroxyvalerate), styrene-isobutylene-styrene triblock copolymer, poly(ethylene-co-vinyl acetate), and a combination thereof; and

wherein B is selected from the group consisting of a linear or branched alkyl chain, polysilanes, polysiloxanes, poly(dimethylsiloxane), a linear or branched perfluoro chain, and a combination thereof.

5. (Original) The method of claim 1 wherein the low surface energy polymer is selected from the group consisting of organosilicone surfactants, block copolymers of alkyl chains with polyglycol chains, fluoro surfactants, block copolymers of polydimethylsiloxane and polycaprolactone, polyurethanes end-capped with long chain perfluoro alcohols, poly(ester-urea)urethanes end-capped with long chain perfluoroalcohols, polyurethanes end-capped with alkyl chains, polyurethanes end-capped with polydimethylsiloxane, copolymers of polycaprolactone and fluoroalcohols, and combinations thereof.

6. (Original) The method of any of claims 1-5 wherein the composition further comprises a bioactive agent.

7. (Original) The method of claim 6 wherein the bioactive agent is selected from the group consisting of Everolimus, paclitaxel, docetaxel, estradiol, steroidal anti-inflammatory agents, antibiotics, anticancer agents, nitric oxide donors, super oxide dismutases, super oxide

dismutases mimics, 4-amino-2,2,6,6-tetramethylpiperidine-1-oxyl (4-amino-TEMPO), ABT-578, tacrolimus, pimecrolimus, batimastat, mycophenolic acid, clobetasol, dexamethasone, rapamycin, 40-*O*-(3-hydroxy)propyl-rapamycin, 40-*O*-[2-(2-hydroxy)ethoxy]ethyl-rapamycin, or 40-*O*-tetrazole-rapamycin, antiproliferative agents, non-steroidal anti-inflammatory agents, immunosuppressive agents, antimigratory agents, and a combination thereof.

8. (Previously presented) A method for forming a poly(ester amide) (PEA) coating with enhanced mechanical and release rate properties, comprising:

applying to an implantable device a solution or suspension of a composition comprising a PEA and at least one low surface energy polymer additive, and

forming a coating on the implantable device comprising PEA and the at least one low surface energy polymer additive,

wherein the at least one low surface energy polymer additive comprises a PEA miscible block or PEA miscible backbone.

9. (Original) The method of claim 8 wherein the at least one low surface energy polymer additive is selected from the group consisting of Teflon (poly(tetrafluoroethylene), FEP (fluorinated ethylene-propylene), poly(tetrafluoroethylene-co-hexafluoropropene), PVDF (polyvinylidene fluoride), poly(fluoroalkenes), polysilanes, polysiloxanes, silicone (polydimethylsiloxane), hydrocarbon polymers, polyethylene, polypropylene, polystyrene, polybutadiene and combinations thereof.

10. (Original) The method of claims 8 or 9 wherein the composition further comprises a bioactive agent.

11. (Original) The method of claim 10 wherein the bioactive agent is selected from the group consisting of Everolimus, paclitaxel, docetaxel, estradiol, steroidal anti-inflammatory

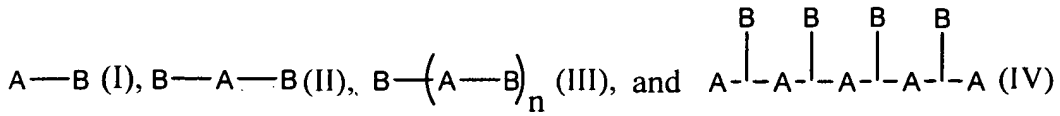
agents, antibiotics, anticancer agents, nitric oxide donors, super oxide dismutases, super oxide dismutases mimics, 4-amino-2,2,6,6-tetramethylpiperidine-1-oxyl (4-amino-TEMPO), ABT-578, tacrolimus, pimecrolimus, batimastat, mycophenolic acid, clobetasol, dexamethasone, rapamycin, 40-*O*-(3-hydroxy)propyl-rapamycin, 40-*O*-[2-(2-hydroxy)ethoxy]ethyl-rapamycin, or 40-*O*-tetrazole-rapamycin, antiproliferative agents, non-steroidal anti-inflammatory agents, immunosuppressive agents, antimigratory agents, and a combination thereof.

12. (Previously presented) A coating composition for coating an implantable device comprising a poly(ester amide) (PEA) and a low surface energy, surface blooming polymer,

wherein the low surface energy, surface blooming polymer comprises a PEA miscible block or PEA miscible backbone.

13. (Previously presented) The composition of claim 13 wherein the low surface energy, surface blooming polymer is selected from the group consisting of a block copolymer comprising a block miscible with the PEA and a hydrophobic block, a polymer comprising a backbone miscible with PEA and hydrophobic pendant groups, and a combination thereof.

14. (Original) The composition of claim 12 wherein the low surface energy, surface blooming polymer is selected from the group consisting of formulae I-IV of the following structure:



wherein A is a PEA miscible block or PEA miscible backbone, and

wherein B is selected from the group consisting of a surface blooming block and a surface blooming pendant group.

15. (Original) The composition of claim 14 wherein A is selected from the group consisting of polyurethane, poly(ester-urea) urethane, polyglycol, poly(tetramethylene glycol), poly(propylene glycol), polycaprolactone, ethylene vinyl alcohol copolymer, poly(butyl methacrylate), poly(methacrylate), poly(acrylate), and a combination thereof; and

wherein B is selected from the group consisting of a linear or branched alkyl chain, polysilanes, polysiloxanes, poly(dimethylsiloxane), a linear or branched perfluoro chain, and a combination thereof.

16. (Original) The composition of claim 15 wherein the low surface energy, surface blooming polymer is selected from the group consisting of organosilicone surfactants, block copolymers of alkyl chains with polyglycol chains, fluoro surfactants, block copolymers of polydimethylsiloxane and polycaprolactone, polyurethanes endcapped with long chain perfluoro alcohols, poly(ester-urea)urethanes endcapped with long chain perfluoro alcohols, polyurethanes endcapped with alkyl chains, polyurethanes endcapped with polydimethylsiloxane, and combinations thereof.

17. (Original) The composition of any of claims 12-16 further comprising a bioactive agent.

18. (Original) The composition of claim 17 wherein the bioactive agent is selected from the group consisting of Everolimus, paclitaxel, docetaxel, estradiol, steroidal anti-inflammatory agents, antibiotics, anticancer agents, nitric oxide donors, super oxide dismutases, super oxide dismutases mimics, 4-amino-2,2,6,6-tetramethylpiperidine-1-oxyl (4-amino-TEMPO), ABT-578, tacrolimus, pimecrolimus, batimastat, mycophenolic acid, clobetasol, dexamethasone, rapamycin, 40-*O*-(3-hydroxy)propyl-rapamycin, 40-*O*-[2-(2-hydroxy)ethoxy]ethyl-rapamycin, or 40-*O*-tetrazole-rapamycin, antiproliferative agents, non-

steroidal anti-inflammatory agents, immunosuppressive agents, antimigratory agents, and a combination thereof.

19. (Previously presented) A coating composition for coating an implantable device comprising a poly(ester amide) (PEA) and at least one low surface energy polymer additive, wherein the at least one low surface energy polymer additive comprises a PEA miscible block or PEA miscible backbone.

20. (Original) The composition of claim 19 wherein the at least one low surface energy polymer additive is selected from the group consisting of Teflon (poly(tetrafluoroethylene), FEP (fluorinated ethylene-propylene), poly(tetrafluoroethylene-co-hexafluoropropene), PVDF (polyvinylidene fluoride), poly(fluoroalkenes), polysilanes, polysiloxanes, silicone (polydimethylsiloxane), hydrocarbon polymers, polyethylene, polypropylene, polystyrene, polybutadiene and combinations thereof.

21. (Original) The composition of claims 19 or 20 further comprising a bioactive agent.

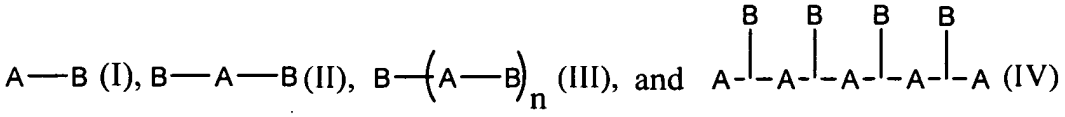
22. (Original) The composition of claim 21 wherein the bioactive agent is selected from the group consisting of Everolimus, paclitaxel, docetaxel, estradiol, steroidal anti-inflammatory agents, antibiotics, anticancer agents, nitric oxide donors, super oxide dismutases, super oxide dismutases mimics, 4-amino-2,2,6,6-tetramethylpiperidine-1-oxyl (4-amino-TEMPO), ABT-578, tacrolimus, pimecrolimus, batimastat, mycophenolic acid, clobetasol, dexamethasone, rapamycin, 40-*O*-(3-hydroxy)propyl-rapamycin, 40-*O*-[2-(2-hydroxy)ethoxy]ethyl-rapamycin, or 40-*O*-tetrazole-rapamycin, antiproliferative agents, non-steroidal anti-inflammatory agents, immunosuppressive agents, antimigratory agents, and a combination thereof.

23. (Previously presented) An implantable device comprising a coating which comprises a poly(ester amide) (PEA) and a low surface energy, surface blooming polymer,

wherein the low surface energy, surface blooming polymer comprises a PEA miscible block or PEA miscible backbone.

24. (Previously presented) The implantable device of claim 23 wherein the low surface energy, surface blooming polymer is selected from the group consisting of a block copolymer comprising a block miscible with the PEA and a hydrophobic block, a polymer comprising a backbone miscible with PEA and hydrophobic pendant groups, and a combination thereof.

25. (Original) The implantable device of claim 24 wherein the low surface energy, surface blooming polymer is selected from the group consisting of formulae I-IV of the following structure:



wherein A is a PEA miscible block or PEA miscible backbone, and

wherein B is selected from the group consisting of a surface blooming block and a surface blooming pendant group.

26. (Original) The implantable device of claim 25 wherein A is selected from the group consisting of polyurethane, poly(ester-urea) urethane, polyglycol, poly(tetramethylene glycol), poly(propylene glycol), polycaprolactone, ethylene vinyl alcohol copolymer, poly(butyl methacrylate), poly(methacrylate), poly(acrylate), and a combination thereof; and

wherein B is selected from the group consisting of a linear or branched alkyl chain, polysilanes, polysiloxanes, poly(dimethylsiloxane), a linear or branched perfluoro chain, and a combination thereof.

27. (Original) The implantable device of claim 26 wherein the low surface energy, surface blooming polymer is selected from the group consisting of organosilicone surfactants, block copolymers of alkyl chains with polyglycol chains, fluoro surfactants, block copolymers of polydimethylsiloxane and polycaprolactone, polyurethanes endcapped with long chain perfluoro alcohols, poly(ester-urea)urethanes endcapped with long chain perfluoro alcohols, polyurethanes endcapped with alkyl chains, polyurethanes endcapped with polydimethylsiloxane, and combinations thereof.

28. (Original) The implantable device of any of claims 23-27 further comprising a bioactive agent.

29. (Original) The implantable device of claim 28 wherein the bioactive agent is selected from the group consisting of Everolimus, paclitaxel, docetaxel, estradiol, steroidal anti-inflammatory agents, antibiotics, anticancer agents, nitric oxide donors, super oxide dismutases, super oxide dismutases mimics, 4-amino-2,2,6,6-tetramethylpiperidine-1-oxyl (4-amino-TEMPO), ABT-578, tacrolimus, pimecrolimus, batimastat, mycophenolic acid, clobetasol, dexamethasone, rapamycin, 40-*O*-(3-hydroxy)propyl-rapamycin, 40-*O*-[2-(2-hydroxy)ethoxy]ethyl-rapamycin, or 40-*O*-tetrazole-rapamycin, antiproliferative agents, non-steroidal anti-inflammatory agents, immunosuppressive agents, antimigratory agents, and a combination thereof.

30. (Previously presented) An implantable device comprising a coating which comprises a poly(ester amide) (PEA) and at least one low surface energy polymer additive,

wherein the at least one low surface energy polymer additive comprises a PEA miscible block or PEA miscible backbone.

31. (Original) The implantable device of claim 30 wherein the at least one low surface energy polymer additive is selected from the group consisting of Teflon (poly(tetrafluoroethylene), FEP (fluorinated ethylene-propylene), poly(tetrafluoroethylene-co-hexafluoropropene), PVDF (polyvinylidene fluoride), poly(fluoroalkenes), polysilanes, polysiloxanes, silicone (polydimethylsiloxane), hydrocarbon polymers, polyethylene, polypropylene, polystyrene, polybutadiene and combinations thereof.

32. (Original) The implantable device of claims 30 or 31 further comprising a bioactive agent.

33. (Original) The implantable device of claim 32 wherein the bioactive agent is selected from the group consisting of Everolimus, paclitaxel, docetaxel, estradiol, steroidal anti-inflammatory agents, antibiotics, anticancer agents, nitric oxide donors, super oxide dismutases, super oxide dismutases mimics, 4-amino-2,2,6,6-tetramethylpiperidine-1-oxyl (4-amino-TEMPO), ABT-578, tacrolimus, pimecrolimus, batimastat, mycophenolic acid, clobetasol, dexamethasone, rapamycin, 40-*O*-(3-hydroxy)propyl-rapamycin, 40-*O*-[2-(2-hydroxy)ethoxy]ethyl-rapamycin, or 40-*O*-tetrazole-rapamycin, antiproliferative agents, non-steroidal anti-inflammatory agents, immunosuppressive agents, antimigratory agents, and a combination thereof.

34. (Original) The implantable device of claim 23 which is a stent.

35. (Original) The implantable device of claim 24 which is a stent.

36. (Original) The implantable device of claim 25 which is a stent.

37. (Original) The implantable device of claim 26 which is a stent.

38. (Original) The implantable device of claim 27 which is a stent.

39. (Original) The implantable device of claim 30 which is a stent.

40. (Original) The implantable device of claim 31 which is a stent.

41. (Original) The implantable device of claim 28 which is a drug-eluting stent.

42. (Original) The implantable device of claim 29 which is a drug-eluting stent.

43. (Original) The implantable device of claim 32 which is a drug-eluting stent.

44. (Original) The implantable device of claim 33 which is a drug-eluting stent.

45. (Original) A method of treating a disorder in a human being by implanting in the human being a stent as defined in claim 34,

wherein the disorder is selected from the group consisting of atherosclerosis, thrombosis, restenosis, hemorrhage, vascular dissection or perforation, vascular aneurysm, vulnerable plaque, chronic total occlusion, claudication, anastomotic proliferation for vein and artificial grafts, bile duct obstruction, ureter obstruction, tumor obstruction, and combinations thereof.

46. (Original) A method of treating a disorder in a human being by implanting in the human being a stent as defined in claim 35,

wherein the disorder is selected from the group consisting of atherosclerosis, thrombosis, restenosis, hemorrhage, vascular dissection or perforation, vascular aneurysm, vulnerable plaque, chronic total occlusion, claudication, anastomotic proliferation for vein and artificial grafts, bile duct obstruction, ureter obstruction, tumor obstruction, and combinations thereof.

47. (Original) A method of treating a disorder in a human being by implanting in the human being a stent as defined in claim 36,

wherein the disorder is selected from the group consisting of atherosclerosis, thrombosis, restenosis, hemorrhage, vascular dissection or perforation, vascular aneurysm, vulnerable plaque,

chronic total occlusion, claudication, anastomotic proliferation for vein and artificial grafts, bile duct obstruction, ureter obstruction, tumor obstruction, and combinations thereof.

48. (Original) A method of treating a disorder in a human being by implanting in the human being a stent as defined in claim 37,

wherein the disorder is selected from the group consisting of atherosclerosis, thrombosis, restenosis, hemorrhage, vascular dissection or perforation, vascular aneurysm, vulnerable plaque, chronic total occlusion, claudication, anastomotic proliferation for vein and artificial grafts, bile duct obstruction, ureter obstruction, tumor obstruction, and combinations thereof.

49. (Original) A method of treating a disorder in a human being by implanting in the human being a stent as defined in claim 38,

wherein the disorder is selected from the group consisting of atherosclerosis, thrombosis, restenosis, hemorrhage, vascular dissection or perforation, vascular aneurysm, vulnerable plaque, chronic total occlusion, claudication, anastomotic proliferation for vein and artificial grafts, bile duct obstruction, ureter obstruction, tumor obstruction, and combinations thereof.

50. (Original) A method of treating a disorder in a human being by implanting in the human being a stent as defined in claim 39,

wherein the disorder is selected from the group consisting of atherosclerosis, thrombosis, restenosis, hemorrhage, vascular dissection or perforation, vascular aneurysm, vulnerable plaque, chronic total occlusion, claudication, anastomotic proliferation for vein and artificial grafts, bile duct obstruction, ureter obstruction, tumor obstruction, and combinations thereof.

51. (Original) A method of treating a disorder in a human being by implanting in the human being a stent as defined in claim 42,

wherein the disorder is selected from the group consisting of atherosclerosis, thrombosis, restenosis, hemorrhage, vascular dissection or perforation, vascular aneurysm, vulnerable plaque, chronic total occlusion, claudication, anastomotic proliferation for vein and artificial grafts, bile duct obstruction, ureter obstruction, tumor obstruction, and combinations thereof.

52. (Original) A method of treating a disorder in a human being by implanting in the human being a stent as defined in claim 44,

wherein the disorder is selected from the group consisting of atherosclerosis, thrombosis, restenosis, hemorrhage, vascular dissection or perforation, vascular aneurysm, vulnerable plaque, chronic total occlusion, claudication, anastomotic proliferation for vein and artificial grafts, bile duct obstruction, ureter obstruction, tumor obstruction, and combinations thereof.

53. (Previously presented) The method of claim 1, wherein the coating is biologically benign.

54. (Previously presented) The method of claim 8, wherein the coating is biologically benign.

55. (Previously presented) The coating of claim 12, which is biologically benign.

56. (Previously presented) The coating of claim 19, which is biologically benign.

57. (Previously presented) The implantable device of claim 23, wherein the coating is biologically benign.

58. (Previously presented) The implantable device of claim 30, wherein the coating is biologically benign.

Remarks

Claims 1-58 are pending. Claims 1-58 are rejected.

Rejections under 35 U.S.C. § 103(a)

Claim 4 is rejected under 35 U.S.C. §103(a) as being obvious over Roby (WO 98/32398) in view of U.S. publication No. 2002/0107330 by Pinhcuck et al ("Pinhcuck").

Claim 4 is drawn to a method of forming a coating on a medical device. The coating includes a PEA polymer and a low energy, surface blooming polymer, which has a PEA miscible block or PEA miscible backbone. The low energy, surface blooming polymer includes A and B blocks as defined in claim 4.

Roby discloses the preparation of a poly(ester amide) (PEA) polymer that can be used for fabrication of surgical devices. However, there is no teaching in Roby of a method of forming a coating comprising applying to an implantable device a composition that comprises a PEA polymer **and a low surface energy, surface blooming polymer** that includes a PEA miscible block or PEA miscible backbone. Nor does Roby recognize the need to improve the properties of a coating formed of a PEA polymer using **a low surface energy, surface blooming polymer**.

Pinhcuck discloses coatings that can be formed of a polymer that can include an A block and a B block. The A block can be a polyolefin, and the B block can be from a methacrylate monomer. Pinhcuck does not describe or teach using a polymer blend to form a coating. Nor does Pinhcuck recognize the need to improve the properties of a coating. Nor does Pinhcuck recognize that the properties of a coating including a PEA polymer can be improved using **a low surface energy, surface blooming polymer**.

Therefore, Roby and Pinhcuck each fail to provide motivation for a person of ordinary skill in the art to combine these two references. Even if they did, for argument purposes, Roby

and Pinhcuck would not lead a person of ordinary skill in the art to have a reasonable expectation of success of the subject matter of claim 4 since both Roby and Pinhcuck fail to recognize that the properties of a coating including a PEA polymer can be improved using **a low surface energy, surface blooming polymer**. As such, Roby and Pinhcuck would not make claim 4 *prima facie* obvious under 35 U.S.C. §103(a) (see MPEP §2141).

Claims 1-3, and 5-58 are rejected under 35 U.S.C. §103(a) as being obvious over Pacetti (WO 03/022323) in view of Roby.

Claim 1 defines a method for forming a poly(ester amide) (PEA) coating with enhanced mechanical and release rate properties. The method includes (a) applying to an implantable device a solution or suspension of a composition comprising **PEA** and **a low surface energy, surface blooming polymer**, and (b) forming a coating on the implantable device comprising PEA and the low surface energy, surface blooming polymer. The low surface energy, surface blooming polymer **includes a PEA miscible block or PEA miscible backbone**.

Pacetti describes a coating for reducing the release rate of a therapeutic agent from the coating. The coating includes a polymer capable of maintaining its crystalline lattice structure while the therapeutic agent is released from the coating. As the Examiner correctly notes, Pacetti does not describe a coating that includes a PEA. Nor does Pacetti describe or teach forming a coating comprising applying to an implantable device a composition that comprises a PEA polymer **and a low surface energy, surface blooming polymer** that includes a PEA miscible block or PEA miscible backbone. Nor does Pacetti recognize the need to improve the properties of a coating formed of a PEA polymer using **a low surface energy, surface blooming polymer**.

As discussed above, Roby discloses the preparation of a poly(ester amide) (PEA) polymer that can be used for fabrication of surgical devices. However, Roby does not describe or teach forming a coating comprising applying to an implantable device a composition that comprises a PEA polymer **and a low surface energy, surface blooming polymer** that includes a PEA miscible block or PEA miscible backbone. Nor does Roby recognize the need to improve the properties of a coating formed of a PEA polymer using **a low surface energy, surface blooming polymer**.

The Examiner alleges that Applicants own teaching that a polyurethane with a polydimethylsiloxane soft segment would meet the defintion of the low energy, surface blooming polymer, thus rendering the claims of the instant application obvious. Applicants respectfully point out that polyurethane **WAS DELETED FROM THE CLAIMS** and is no longer relevant to the claims of the instant application.

In sum, Pacetti and Roby fail to teach or suggest each and every element of the coating defined by claim 1. Therefore, claim 1 is patentably allowable over Pacetti and Roby under 35 U.S.C. 103(a). Claims 2, 3 and 5-7 and 53 depend from claim 1 and are patentable over Pacetti and Roby under 35 U.S.C. 103(a) for at least the same reason.

Claim 8 defines a method of forming a coating having a PEA polymer and at least one low surface energy polymer additive. The at least one low surface energy polymer additive comprises a PEA miscible block or PEA miscible backbone. As discussed above, Pacetti and Roby fail to teach or suggest each and every element of the coating defined by claim 8. Therefore, claim 8 is patentably allowable over Pacetti and Roby under 35 U.S.C. 103(a). Claims 9-11 and 54 depend from claim 8 and are patentable over Pacetti and Roby under 35 U.S.C. 103(a) for at least the same reason.

Claim 12 defines coating composition for coating an implantable device. The composition comprises a poly(ester amide) (PEA) and a low surface energy, surface blooming polymer. The low surface energy, surface blooming polymer comprises a PEA miscible block or PEA miscible backbone. As discussed above, Pacetti and Roby fail to teach or suggest each and every element of the coating defined by claim 12. Therefore, claim 12 is patentably allowable over Pacetti and Roby under 35 U.S.C. 103(a). Claims 13-18 and 55 depend from claim 12 and are patentable over Pacetti and Roby under 35 U.S.C. 103(a) for at least the same reason.

Claim 19 defines a coating having a PEA polymer and at least one low surface energy polymer additive. The at least one low surface energy polymer additive comprises a PEA miscible block or PEA miscible backbone. As the discussion of claim 8 shows, Pacetti and Roby fail to teach or suggest each and every element of the coating defined by claim 19. Therefore, claim 19 is patentably allowable over Pacetti and Roby under 35 U.S.C. 103(a). Claims 20-22 and 56 depend from claim 19 and are patentable over Pacetti and Roby under 35 U.S.C. 103(a) for at least the same reason.

Claim 23 defines an implantable device comprising a coating which comprises a poly(ester amide) (PEA) and a low surface energy, surface blooming polymer. The low surface energy, surface blooming polymer comprises a PEA miscible block or PEA miscible backbone. As discussed above, Pacetti and Roby fail to teach or suggest each and every element of the coating defined by claim 23. Therefore, claim 23 is patentably allowable over Pacetti and Roby under 35 U.S.C. 103(a). Claims 24-29, 34-38, 41, 42, 45-49, 51 and 57 depend from claim 23 and are patentable over Pacetti and Roby under 35 U.S.C. 103(a) for at least the same reason.

Claim 30 defines an implantable device comprising a coating having a PEA polymer and at least one low surface energy polymer additive. The at least one low surface energy polymer additive comprises a PEA miscible block or PEA miscible backbone. As discussed above, Pacetti and Roby fail to teach or suggest each and every element of the coating defined by claim 30. Therefore, claim 30 is patentably allowable over Pacetti and Roby under 35 U.S.C. 103(a). Claims 31-33, 39, 40, 43, 44, 50, 52 and 58 depend from claim 30 and are patentable over Pacetti and Roby under 35 U.S.C. 103(a) for at least the same reason.

The undersigned authorizes the examiner to charge any fees that may be required or credit of any overpayment to be made to Deposit Account No. 07-1850.

CONCLUSION

The present communication presents no new issue. Withdrawal of the rejection and allowance of all the claims are respectfully requested. **If the Examiner has any suggestions or amendments to the claims to place the claims in condition for allowance, applicant would prefer a telephone call to the undersigned attorney for approval of an Examiner's amendment.** If the Examiner has any questions or concerns, the Examiner is invited to telephone the undersigned attorney at (415) 393-9885.

Date: January 7, 2008
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Respectfully submitted,

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10/750,139	06/03/2004	Jessica R. DesNoyer	50623.326	2159

7590 01/30/2008

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EXAMINER	
ROGERS, JAMES WILLIAM	

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ADVISORY ACTION

RESPONSE DUE: Appeal brief
4 MONTH DATE: due 3/7/08
5 MONTH DATE: _____
DROP DEAD DATE: _____

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DOCKETED: N/A

FEB 04 2008

BY: AV Atty: ZL
SQUIRE, SANDERS & DEMPSEY

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/750,139	Applicant(s) DESNOYER ET AL.	
	Examiner James W. Rogers, Ph.D.	Art Unit 1618	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 07 January 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *07 January 2008*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: _____.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

Continuation of 11. does NOT place the application in condition for allowance because: applicants remarks on the rejections under 35 U.S.C 103(a) over Roby et al. (WO 98/32398 A1) in view of Pinhcuck et al. (US 2002/0107330) and over Pacetti (WO 03/022323 A1) and in view of Roby et al. (WO 98/32398 A1) are not persuasive.

Applicants firstly assert that Roby does not disclose a method of forming a coating comprising applying to an implantable device a composition that comprises a PEA polymer and a low surface energy, surface blooming polymer that includes a PEA miscible block or PEA miscible backbone. Applicant also assert that neither Roby nor Pinhcuck recognize the need to improve the properties of a coating formed of a PEA polymer using a low surface energy, surface blooming polymer. Applicants assert that Pinhcuck does not describe or teach a polymer blend to form a coating nor does the reference recognize the need to improve the properties of the coating. Applicants therefore surmise that there is no motivation for a person of ordinary skill to combine the references nor is there a reasonable expectation of success.

The relevance of these assertions is unclear. Firstly teaching, suggestion or motivation are not the only considerations when determining whether two or more references can be combined, as detailed in the recent decision of KSR International Co. v.Teleflex Inc. (KSR), 550 U.S. ___, 82 USPQ2d 1385 (2007). In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Clearly the combination of references would yield a coating for a medical device comprising the PEA polymer of Roby and the biocompatible A-B block copolymer of Pinchuck that is the same as applicants claimed low surface energy polymer of claim 4. It is generally considered to be prime facie obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose in order to form a composition that is to be used for an identical purpose. Clearly one of ordinary skill in the art could envision that since the polymers described were both useful for the same purpose one would expect that they could be combined and yield predictable results.

Applicants secondly assert that Pacetti does not disclose PEA as pointed out by the examiner nor do the Pacetti and Roby references disclose a coating applied to an implantable device comprising a low surface energy, surface blooming polymer that includes a PEA miscible block or PEA miscible backbone. Applicant also assert that neither Pacetti nor Roby recognize the need to improve the properties of a coating formed of a PEA polymer using a low surface energy, surface blooming polymer. Applicants also seem to imply that since polyurethane was deleted from the claims (examiner notes only claim 4 made this deletion) polyurethane with a polydimethylsiloxanes soft segment would not longer read on their claims. Thus applicants surmise that the combination of references do not teach all of the claimed elements within independent claims 1,8,12,19,23 and 30.

The relevance of these assertions is unclear. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Since by combination the two references disclose the same type of polymers and the same type of polymer additives the claim limitation is obviously met because the same compounds will have the same miscibility properties. Roby discloses PEA polymers in coating surgical devices while Pacetti discloses polyurethanes with a polydimethylsiloxane soft segment useful in coating stents. From applicants own specification polyurethanes with a polydimethylsiloxane soft segment would meet a low surface energy surface blooming polymer or polymer additive that includes a miscible PEA block or backbone. See page 3 lin 15-page 4 lin 14 of applicants specification. Regarding applicant's assertion that polyurethane was deleted from the claims, this has no bearing on the claims rejected by Pacetti and Roby, the only claim that included this limitation was claim 4 which was not rejected over the references above. Since the claims rejected over Pacetti and Roby do not exclude a polymer that contains polyurethane with a polydimethyl soft segment it would still read on applicants claims because as described above such a polymer would meet a low surface energy surface blooming polymer or polymer additive. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case or either anticipation or obviousness has been established, Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable.

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